FORMS VERSION D SERIES UPDATED MARCH 25, 2016



FELLOWSHIP INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES

SF424 (R&R) APPLICATION PACKAGES

Guidance developed and maintained by NIH for preparing and submitting applications via Grants.gov to NIH and other PHS agencies using the SF424 (R&R)

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F.100 - How to Use the Application Instructions

Tour the new Application Guide!



- Become familiar with the application submission process.
 - Understanding the information in the Application Process section of this guide, including required registrations, is critical to successfully submitting your application.
- Use these instructions in conjunction with your funding opportunity announcement (FOA).
 - Remember that the funding opportunity announcement instructions always supersede these application instructions.
- Pick a format.
 - Comprehensive. Use the general (G) instructions, available in both HTML and PDF format, to complete the application forms for any type of grant program.
 - **Program-specific.** Take advantage of the filtered PDFs to see just the instructions you need for research (R), career development (K), training (T), fellowship (F), multi-project (M) or SBIR/STTR (B) applications.
- · Determine which instructions are needed.
 - Refer to <u>Selecting the Correct Application Instructions</u> to match the activity code of your funding opportunity to the needed instructions (e.g., the R01 activity code maps to the Research (R) instructions).
 - Consult the Program Overview section for context for program specific instructions.
- Follow both standard and program-specific guidance.
 - Follow the standard instruction for each field, as well as, any additional program-specific instructions.
- Complete only the forms included with the funding opportunity.
- Refer to significant changes section for the most recent changes to these application instructions.
 - Review <u>changes to NIH policy</u> since the posting of the application guide.

F.110 - Application Process

Quick Links

- Prepare to Apply and Register
- Format and Write
- Submission Process
- Due Dates and Submission Deadlines

- After Submission
- Resources
- Information Collection

Prepare to Apply and Register

Understand Key Systems and Roles

Learn about the main systems involved in application submission and the role you and your colleagues play in the submission process. <u>Grants.gov</u>, <u>eRA Commons</u>, <u>ASSIST</u>.

 $\frac{\text{https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/key-systems-and-roles.htm}$

Get Registered!

Determine your registration status. Organizations, organizational representatives, investigators, and others need to register in multiple federal systems in order to apply. Registration can take 6 weeks or more to complete. Start today!

http://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/registration.htm

Find and Understand Funding Opportunities

Identify the right funding opportunity announcement for you and your research and learn about the key information you will find in the opportunity.

http://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/find-and-understand-foas.htm

Identify the Type of Application Submission

Are you submitting a new, renewal, revision, or resubmission application? Learn about special submission requirements for revisions and resubmissions.

http://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/type-of-application-submission.htm

Choose a Submission Option

Determine which system is most convenient for your submission to NIH: NIH's ASSIST on-line application submission system, Grants.gov downloadable forms, or your organization may have their own submission system.

 $\underline{\text{http://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/choose-asubmission-option.htm}$

Obtain Software

Applicants must have the free Adobe Reader software, a PDF generator, as well as web browser to submit an application. Learn which versions are compatible with our systems.

 $\frac{\text{http://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/obtainsoftware.htm}{}$

Format and Write

Write Your Application

Read tips for developing a strong application that helps reviewers evaluate its science and merit.

http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/write-your-application.htm

Develop Your Budget

Learn about the kinds of costs you may include in your budget submission, the difference between modular and detailed budgets, and more.

http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm

Format Attachments

Follow these requirements for preparing the documents you attach to your application, including criteria for the pdf files, fonts, margins, headers and footers, paper size, citations, format pages and more.

http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm

Refer to Table of Page Limits

Follow the page limits specified in this table unless instructed otherwise by the funding opportunity announcement to which you are applying.

http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/table-of-page-limits.htm

Utilize Biosketch, Data Tables and Other Format Pages

A comprehensive listing of the format pages you will use when you attach various files to your application, including instructions for submission of a reference letter.

Submission Process

Submit, Track and View Your Application

Learn how to submit your application to Grants.gov, and your responsibility for tracking your application and viewing the application image in the eRA Commons before the application deadline. If you can't view your application in eRA Commons, we can't review it.

http://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/submit-track-view.htm

Learn How We Check Your Application for Completeness

It is important that all applications being reviewed together adhere to the same rules. Consequently, your application will be checked at Grants.gov, by eRA systems and finally by federal staff before it is referred for review.

 $\frac{\text{http://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/check-your-application.htm}$

Submit a Changed/Corrected Application

You will need to submit a changed/corrected application to correct issues you find, or our systems find with your application. Learn how and when you may submit a change/corrected application.

 $\underline{\text{http://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/changed-corrected-application.htm}\\$

Submit a Reference letter

Some types of programs require the submission of reference letters by the referee. Referees must submit these letters by the application deadline in order to be considered as part of the application. Learn the process and policies for submission of reference letters.

http://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/reference-letter.htm

Due Dates and Submission Deadlines

Due Dates

View standard due dates for NIH programs. The FOA will identify if a specific due date should be used.

 $\underline{\text{http://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/standard-due-dates.htm}$

Submission Policies

Learn the nuances of submission policies, including when we might allow late applications, what to do if due dates fall on a weekend or holiday, whether we allow post-submission materials, how to document system issues, the rules around resubmission applications, and more.

http://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/application-submission-policies.htm

Guidelines for Applicants Experiencing System Issues

Experiencing system issues with ASSIST, Grants.gov, SAM, or NIH's eRA Commons that you believe threaten your ability to submit on time? NIH will not penalize applicants who experience confirmed issues beyond their control with federal systems. You must report the problem before the submission deadline.

http://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/guidelines-for-applicants-experiencing-system-issues.htm

After Submission

Receipt and Referral

Understand how and when applications are given an application identification number and assigned to a review group and an NIH institute or center for possible funding.

http://grants.nih.gov/grants/receipt_referral.htm

Peer Review

Learn about our two phase peer review system, including initial peer review, Council review, review criteria, scoring, summary statements, and more.

http://grants.nih.gov/grants/peer_review_process.htm

Pre-Award Process

Learn what happens between peer review through award for applicants whose applications have been deemed highly meritorious in the scientific peer review process. Be ready, if you received a great score in peer review we will ask you to submit just-in-time information.

http://grants.nih.gov/grants/pre-award-process.htm

Post Award Monitoring and Reporting

If you are the recipient of a grant from the NIH, there is a great deal of information that you will need in order to be a successful steward of federal funds. This page provides a brief overview of grantee monitoring and reporting requirements.

http://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm

Resources

News - Items of Interest

The eSubmission Items of Interest provide comprehensive information on the changes impacting application development and submission in a friendly, informal format.

https://grants.nih.gov/grants/how-to-apply-application-quide/resources/news-items-of-interest.htm

Annotated Form Sets

These handy documents are a great visual resource for understanding many of the business rule checks we will run against your submitted application.

http://grants.nih.gov/grants/how-to-apply-application-guide/resources/annotated-form-sets.htm

Contacting NIH Staff

NIH staff is here to help. We strongly encourage applicants and grantees to communicate with us throughout the grant life cycle. Understanding the roles of NIH staff can help you contact the right person at each phase of the application and award process.

http://grants.nih.gov/grants/how-to-apply-application-guide/resources/contacting-nih-staff.htm

Contacting Staff at Other PHS Agencies

Applicants are strongly encouraged to communicate with agency staff throughout the entire application review and awards process.

 $\frac{https://grants.nih.gov/grants/how-to-apply-application-guide/resources/contacting-staff-at-other-public-health-service-agencies.htm \\$

Information Collection

Authorization

Describes NIH's statutory authorities for awarding grants.

http://grants.nih.gov/grants/authorization.htm

Paperwork Burden

Provides estimated time for completing a grant application.

http://grants.nih.gov/grants/paperwork-burden.htm

Collection of Personal Demographic Data

NIH collects personal data through the eRA Commons Personal Profile. The data is confidential, and is maintained under the Privacy Act record system.

http://grants.nih.gov/grants/collection-of-personal-demographic-data.htm

F.120 - Significant Changes

Modifications include the following:

Application Guide Restructure

- **Forms reordered.** Form instructions have been reordered to match the order of appearance in the application package.
- Consolidated instructions. SBIR/STTR instructions have been incorporated into the general instructions.
- Separated form instructions from application process information. Created an application
 guide landing page that provides at-a-glance access to all form instructions and application process
 information. Links to all grants process information appear in the form instructions as well.
- Combined and streamlined instructions. For Research and Related (R&R) forms, we have
 combined Federal-wide and agency-specific instructions to reduce confusion, contradictions,
 and/or redundant language. Users will no longer see the HHS logo displayed, as all instructions are
 now applicable to NIH and PHS agencies.
- Better integrated mechanism-specific instructions. Variances in instructions for each type of grant program (research, career development, etc.), are now called out and integrated in the general instructions to make them easy to follow.
- New mechanism-specific views of application guide. Use the General (G) instructions to see instructions for all mechanisms in one place. Take advantage of the filtered views to see just the instructions you need for research (R), career development (K), training (T), fellowship (F), multiproject (M) or SBIR/STTR (B) applications.
- New section numbering system. Form instructions will follow the same numbering system for
 each set of instructions. For example, the SF 424 (R&R) Cover Form will always be ".100", and the
 letter preceding it will reflect the specific instructions you are using. For the General (G)
 instructions, this form will be located in G.100; for the Research (R) instructions, this will be R.100;
 and so on.
- New page numbering system. Page numbers will denote which set of instructions you are looking at (e.g., G 56 for page 56 of the General instructions; R 56 for page 56 of the Research (R) instructions; etc.). This distinction will be important when you reference a particular instruction.
- Form screenshots. Provided at the end of each set of instructions for your reference.

SF424 Research and Related (R&R) Form Changes

R&R Other Project Information Form

 A list of referees is no longer required as an Other Attachment on the R&R Other Project Information Form. This information is only required in the cover letter attachment. Reference letters will continue to be submitted through eRA Commons.

R&R Senior/Key Person Profile (Expanded) Form

- Mentors must provide a Commons username for Career applications (See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-082.html)
- Consolidated biosketch instructions for research, institutional research training, institutional career
 development, research education, fellowship, and dissertation awards, as well as diversity
 supplements. Clarified policy requirements. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-080.html.

Forms-D Changes

PHS Assignment Request Form

- · New, optional form
- Provides structured information to NIH referral staff regarding: funding component assignment preference, study section preference, individuals who should not review your application due to conflicts, and scientific areas of expertise needed to review your application
- Complements existing "Cover Letter Attachment" on SF424 (R&R) form
- Added/updated burden statement and form expiration date
- · Updated form instructions

PHS Fellowship Supplemental Form

- New "Applicant's Background and Goals for Fellowship Training" attachment
 - Combines "Doctoral Dissertation and Other Research Experience", "Goals for Training and Career", and "Activities Planned Under Award" attachments into a single attachment
- New "Letters of Support from Collaborators, Contributors, and Consultants" attachment
- New "Description of Institutional Environment and Commitment to Training" attachment
- New "Data Safety Monitoring Plan" attachment
- New "Authentication of Key Biological and/or Chemical Resources" attachment
- New Vertebrate Animals guestions added:
 - · Are animals euthanized? Yes/No
 - If Yes, is method consistent with AVMA guidelines? Yes/No
 - If No to AVMA guidelines, describe method/provide scientific justification
- Updated list of values for the "Field of Training for Current Proposal" field; changed from 4-digit codes to 3-digit codes

- · Updated Citizenship selections
- · Reorganization of attachments
- Format and label changes
- Added/updated burden statement and form expiration date
- Updated form instructions

PHS Inclusion Enrollment Report

- Combines Planned Enrollment Report and Cumulative Inclusion Enrollment Report forms into a single form
- Questions used to identify type of report:
 - Delayed onset study? Yes/No
 - Enrollment Type? Planned/Cumulative (Actual)
 - Using an Existing Dataset or Resource? Yes/No
 - Enrollment Location? Domestic/Foreign
 - · Clinical Trial? Yes/No
 - NIH-Defined Phase II Clinical Trial? Yes/No
- Added/updated burden statement and form expiration date
- · Updated form instructions

F.130 - Program Overview

Quick Links

- Individual Fellowship Applications ("F" Series)

Individual Fellowship Applications ("F" Series)

This section contains instructions and other useful information for preparing Kirschstein NRSA and non-NRSA Fellowship Applications to the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ).

Kirschstein-NRSA Programs: The Kirschstein-NRSA program helps ensure that a diverse pool of highly trained scientists is available in adequate numbers and in appropriate research areas to carry out the Nation's biomedical and behavioral research agenda. Kirschstein-NRSA fellowships are awarded as a result of national competition for research training in specified health-related areas. Certain specialized individual fellowships, such as the predoctoral fellowships (F31 and F30), postdoctoral fellowships (F32), senior fellowships (F33), and other institute-specific fellowship programs are provided under this authority.

Non-NRSA Programs: Fogarty International Center (FIC) and National Library of Medicine (NLM) also have unique funding authorities for fellowships that are not under the Kirschstein-NRSA authority.

Additional fellowship instructions will be denoted by an orange box and "Additional Instructions for Fellowship" heading.

Before Applying:

- **Become familiar with Activity Code:** Applicants should become familiar with the "F" activity code for which support is being requested.
- Refer to specific FOA: Before applying for an F award, applicants should carefully review the
 applicable Funding Opportunity Announcement (FOA) for the fellowship of interest, noting
 especially the eligibility requirements, requirements for a mentor, review criteria, award provisions,
 and any special application instructions. Each FOA contains more specific information associated
 with the award mechanism and includes names of individuals who may be contacted prior to
 submission of an application for additional or clarifying information.
 - Guidelines for NIH fellowships may be found on the NIH Web Site at https://researchtraining.nih.gov/programs/fellowships.
 - Guidelines for the AHRQ fellowships may be found at http://www.ahrq.gov/funding/training-grants/index.html.
- Contact Awarding Component: It is strongly recommended that applicants consult with the
 appropriate NIH IC or AHRQ staff prior to submitting an application as not all predoctoral,
 postdoctoral, and senior fellowships are supported by each IC and AHRQ.

- A list of contacts specifically for extramural training at the NIH ICs can be found at https://researchtraining.nih.gov/tac-roster.
- For contacts at AHRQ, see http://www.ahrq.gov/funding/training-grants/contacts.html.

Follow these instructions for submitting the required reference letters for applicable programs, such as career development and individual fellowship awards:

http://grants.nih.gov/grants/forms/reference-letter.htm. Referees must submit reference letters through the eRA Commons by the application due date.

The following chart provides a list of fellowship activity codes. Since this information is subject to change, prospective applicants are encouraged to review the <u>F-Kiosk</u> for the most current information and links to Funding Opportunity Announcements (FOAs).

Summary of Individual Fellowship Award Programs

Activity Code	Program Description	NRSA?
F05	International Research Fellowships	NO
F30	Individual Predoctoral NRSA for M.D./Ph.D. Fellowships	YES
F31	Predoctoral Individual National Research Service Award	YES
F32	Postdoctoral Individual National Research Service Award	YES
F33	National Research Service Awards for Senior Fellows	YES
F37	Medical Informatics Fellowships	NO
F38	Applied Medical Informatics Fellowships	NO

F.200 - SF 424 (R&R) Form

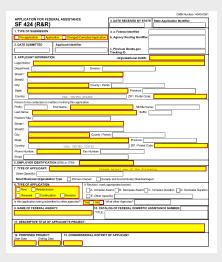
The SF 424 (R&R) Form is used in all grant applications. This form collects information including type of submission, applicant information, type of applicant, and proposed project dates.



Quick Links

- 1. Type of Submission
- 2. Date Submitted and Applicant Identifier
- 3. Date Received by State and State Application Identifier
- 4a. Federal Identifier
- 4b. Agency Routing Identifier
- 4c. Previous Grants.gov Tracking ID
- 5. Applicant Information
- 6. Employer Identification
- 7. Type of Applicant
- 8. Type of Application
- 9. Name of Federal Agency
- 10. Catalog of Federal Domestic Assistance (CFDA)

 Number and Title
- 11. Descriptive Title of Applicant's Project
- 12. Proposed Project
- 13. Congressional District of Applicant
- 14. Program Director/Principal Investigator (PD/PI)
 Contact Information
- 15. Estimated Project Funding
- 16. Is Application Subject to Review by State Executive Order 12372 Process?
- 17. Certification
- 18. SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation
- 19. Authorized Representative
- 20. Pre-Application
- 21. Cover Letter Attachment



1. Type of Submission

This field is required. Check one of the Typecifically noted in a Funding Opportunity Announcement, the Pre-application option e of Submission boxes:

Pre-Application:

Unless spis not used by NIH and other PHS agencies.

Changed/Corrected Application:

This box must be used if you need to submit the same application again to correct system validation errors, application assembly problems, or to incorporate other changes. When submitting a Changed/Corrected Application:

- If submitting after the submission date, include an explanation in the Cover Letter attachment.
- Submitting a Changed/Corrected application replaces the previous submission and removes
 the previous submission from consideration. Once an application has moved forward to
 agency staff following the two-day application viewing window, subsequent
 Changed/Corrected applications will not be accepted unless the application is withdrawn.
 Note that if you are submitting additional grant application materials after the submission
 date some special guidelines may apply. See NIH Guide Notice NOT-OD-10-115
 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-115.html) for the NIH Policy on
 Post-Submission Application Materials.
- When you check the Changed/Correct Application box the Previous Grants.gov Tracking ID becomes a required field.
- Do not use the Changed/Corrected Application box to denote a submission of a resubmission or amended application. That will be indicated in the Type of Application.

2. Date Submitted and Applicant Identifier

The Applicant Identifier field is a control number created by the applicant organization, not the Federal agency.

3. Date Received by State and State Application Identifier

For submissions to NIH and other PHS agencies, leave these fields blank.

4.a. Federal Identifier

When a New Application is being submitted following a Pre-Application, enter the agency-assigned pre-application number, if applicable. If this is a continuation, revision, or renewal application, enter the assigned Federal Identifier number (for example, award number)—even if submitting a Changed/Corrected application.

For submissions to NIH and other PHS agencies, include only the IC and serial number of the previously assigned application/award number (e.g., use CA987654 from 1R01CA987654-01A1). The Federal Identifier is required for Resubmission, Renewal, and Revision applications.

Applicants to NIH and other PHS agencies should complete this field when submitting a resubmission, renewal or revision application. When submitting a "New" application, this field should remain blank.

4.b. Agency Routing Identifier

Unless specifically noted in a program announcement, the Agency Routing Identifier is not used by NIH or other PHS agencies.

4.c. Previous Grants.gov Tracking ID

Enter the previous Grants.gov tracking number, if applicable.

5. Applicant Information

This information is for the Applicant Organization, not a specific individual.

Organizational DUNS:

Enter the DUNS or DUNS+4 number of the applicant organization. This field is required.

For submission to NIH and other PHS agencies, this DUNS must match the number entered in the eRA Commons Institutional Profile for the applicant organization. The applicant AOR is encouraged to confirm that a DUNS has been entered in the eRA Commons Institutional Profile (IPF) prior to submitting an application. If your organization does not already have a DUNS number, you will need to go to the Dun & Bradstreet website at http://fedgov.dnb.com/webform to obtain the number. The same DUNS should be used in the eRA Commons IPF, Grants.gov, System for Award Management (SAM) registration and in the DUNS field in the application.

Legal Name:

Enter the legal name of the applicant which will undertake the assistance activity, enter the complete address of the applicant (including county/parish and country), and name, telephone number, e-mail, and fax of the person to contact on matters related to this application.

Department:

Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization that will undertake the assistance activity.

Division:

Enter the name of the primary organizational division, office, or major subdivision which will undertake the assistance activity.

Street1:

Enter the first line of the street address for the applicant in "Street1" field. This field is required.

Street2:

Enter the second line of the street address for the applicant in the "Street2" field. This field is optional.

City:

Enter the City for address of the applicant. This field is required.

County/Parish:

Enter the county/parish for address of the applicant.

State:

Enter the State where the applicant is located. This field is required if the applicant is located in the United States.

Province:

Enter the province. If "Country" is not Canada, please leave blank.

Country:

Select the country for the applicant address. This field is required.

ZIP Code:

Enter the nine-digit postal code (e.g., ZIP code) of applicant. This field is required if the applicant is located in the United States. This field is required if a State is selected; optional for Province.

Person to be contacted on matters involving this application:

This information is for the Administrative or Business Official, not the PD/PI. This person is the individual to be notified if additional information is needed and/or if an award is made. To avoid potential errors and delays in processing, please ensure that the information provided in this section is identical to the AO profile information contained in the eRA Commons.

Prefix:

Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of the person to contact on matters related to this application.

First Name:

Enter the first (given) name of the person to contact on matters related to this application. This field is required.

Middle Name:

Enter the middle name of the person to contact on matters related to this application.

Last Name:

Enter the last (family) name of the person to contact on matters related to this application. This field is required.

Suffix:

Enter the suffix (e.g., Jr., Sr., Ph.D.) for the person to contact on matters related to this application.

Position/Title:

Enter the Position/Title for the person to contact on matters related to this application.

Street1:

Enter first line of the street address for the person to contact on matters related to this application in the "Street1" field. This field is required.

Street2:

Enter the second line of the street address for the person to contact on matters related to this application in the "Street2" field. This field is optional.

City:

Enter the City for address of the person to contact on matters related to this application. This field is required.

County/Parish:

Enter the county/parish for address of the person to contact on matters related to this application.

State:

Enter the State where the person to contact on matters related to this application is located. This field is required if the applicant is located in the United States.

Province:

Enter the province for the person to contact on matters related to this application. If "Country" is not Canada, please leave blank

Country:

Select the country for the person to contact on matters related to this application address.

ZIP Code:

Enter the nine-digit postal code (e.g., ZIP code) of the person to contact on matters related to this application. This field is required if the performance site location is in the United States.

Phone Number:

Enter the daytime phone number for the person to contact on matters related to this application. This field is required.

Fax Number:

Enter the fax number for the person to contact on matters related to this application.

E-mail:

Enter the e-mail address for the person to contact on matters related to this application.

6. Employer Identification

Enter either TIN or EIN as assigned by the Internal Revenue Service. If your organization is not in the U.S., enter 44-4444444.

If you have a 12-digit EIN established for grant awards from NIH or other PHS agencies, enter all 12 digits (e.g., 1123456789A1); this includes non-U.S. organizations. This field is required.

7. Type of Applicant

Select the appropriate applicant type code. For eligible Agencies of the Federal Government, select X: Other (specify), and then indicate the name of the appropriate Federal agency in the space below. For SBIR/STTR applicant organizations, select R. Small Business. If Small Business is selected as Type of Applicant, then note if the organization is Woman-owned and/or Socially and Economically Disadvantaged.

Other (Specify):

Complete only if "Other" is selected as the Type of Applicant.

Woman Owned:

Check if you are a woman-owned small business - a small business that is at least 51% owned by a woman or women, who also control and operate it.

Socially and Economically Disadvantaged:

Check if you are a socially and economically disadvantaged small business, as determined by the U.S. Small Business Administration pursuant to Section 8(a) of the Small Business Act U.S.C. 637(a).



Additional Instructions for Fellowship:

This information is for the Applicant Organization, not a specific individual AOR or Fellowship PD/PI.

8. Type of Application

Select the type from the following list of existing definitions for NIH and other PHS agencies. Check only one. This field is required.

- New. Check this option when submitting an application for the first time or in accordance with other submission policies. See NOT-OD-14-074.
- **Resubmission.** Check this option when submitting a revised (altered or corrected) or amended application. See also the NIH Policy on Resubmission Applications.
- Renewal. An application requesting additional funding for a period subsequent to that provided by a
 current award. A renewal application competes with all other applications and must be developed
 as fully as though the applicant is applying for the first time.
- *Continuation*. For the purposes of NIH and other PHS agencies, the box for Continuation is only used for specific FOAs.
- Revision. For competing revisions and non-competing administrative supplements.

This field also affects how you complete the Federal Identifier. If "Type of Application" is "New", you can leave the Federal Identifier field blank unless otherwise specified in the funding opportunity announcement.

If "Type of Application" is "Renewal," "Revision," or "Resubmission," enter the IC and serial number of the previously assigned application/award number (e.g., use CA987654 from 1R01CA987654-01A1).



Additional Instructions for Fellowship:

Unless stated in the applicable FOA, individual F awards are usually not renewable nor are they supplemented/revised (contact the awarding institute or center staff if clarification is needed). Therefore, the applicant should generally check "new" or "resubmission." "Renewal" applications are accepted only for a few F programs; thus this value should only be checked if a specific FOA states that Renewals are accepted.

If Revision, mark appropriate box(es). May select more than one:

- 1. Increase Award
- 2. Decrease Award
- 3. Increase Duration
- 4. Decrease Duration
- 5. Other

If "Other" is selected, please specify in the text box provided.

For the purposes of NIH and other PHS agencies, the boxes for options B, C, D, and E will generally not be used and should not be selected unless specifically addressed in a particular FOA

Is this application being submitted to other agencies?

In the field "Is this application being submitted to other agencies?," please check the box "yes" if one or more of the specific aims submitted in your application are also contained in a similar, identical, or essentially identical application submitted to another Federal agency. Indicate the agency or agencies to which the application has been submitted. For additional information, please see NIH Guide Notice NOT-OD-09-100, Reminder and Clarification of NIH Policies on Similar, Identical, or Essentially Identical Applications, Submission of Applications Following RFA Review, and Submission of Applications with a Changed Activity Code http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-100.html. This field is required.

What Other Agencies?

Enter Agency Name

9. Name of Federal Agency

Name the Federal agency from which assistance is being requested with this application. This field is pre-populated from the opportunity package.

10. Catalog of Federal Domestic Assistance (CFDA) Number and Title

This is the Catalog of Federal Domestic Assistance number of the program under which assistance is requested. This field is pre-populated from the opportunity package.

This field may be blank if you are applying to an opportunity that references multiple CFDA numbers. When this field is blank, leave it blank; the field will not allow any data entry. The appropriate CFDA number will be automatically assigned by the agency once the application is assigned to the appropriate awarding component.

11. Descriptive Title of Applicant's Project

Enter a brief descriptive title of the project. This field is required.

A "new" application must have a different title from any other PHS project submitted for the same application due date with the same PD/PI. A "resubmission" or "renewal" application should normally have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title.

A "revision" application must have the same title as the currently funded grant.

NIH and other PHS agencies limit title character length to 200 characters, including the spaces between words and punctuation.

12. Proposed Project

Start Date:

Enter the proposed start date of the project. This field is required.

Ending Date:

Enter the proposed ending date of the project. This field is required.



Additional Instructions for Fellowship:

The requested period of support must be within specified limits for the type of F award requested.

13. Congressional District of Applicant

Enter the Congressional District in the format: 2 character State Abbreviation - 3 character District Number. Examples: CA-005 for California's 5th district, CA-012 for California's 12th district.

If outside the U.S., enter 00-000.

To locate your congressional district, visit the Grants.gov Web site.

For States and U.S. territories with only a single congressional district enter "001" for the district code. For jurisdictions with no representative, enter "099". For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098, PR-098.

14. Program Director/Principal Investigator (PD/PI) Contact Information

If submitting an application reflecting Multiple PD/PIs, the individual designated as the Contact PI must be affiliated in the Commons with the applicant organization should be entered here. See Section F.240 - Senior/Key Person Profile (Expanded) Form for additional instructions for Multiple PD/PIs. To avoid potential errors and delays in processing, please ensure that the information provided in this section is identical to the PD/PI profile information contained in the eRA Commons.

Prefix:

The Project Director/Principal Investigator (PD/PI) is the individual responsible for the overall scientific and technical direction of the project. Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of the PD/PI.

First Name:

Enter the first (given) name of the PD/PI. This field is required.

Middle Name:

Enter the middle name of the PD/PI.

Last Name:

Enter the last (family) name of the PD/PI. This field is required.

Suffix:

Enter the suffix (e.g., Jr., Sr.) of the PD/PI. Do not use this field to record degrees (e.g., Ph.D.). Degrees for the PD/PI are requested separately in the Senior/Key Person Profile.

Position/Title:

Enter the Position/Title of the PD/PI.

Organization Name:

Enter the name of organization for the PD/PI. This field is required.

Department:

Enter the name of primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.

Division:

Enter the name of primary organizational division, office, or major subdivision of the PD/PI.

Street1:

Enter first line of the street address for the PD/PI in the "Street1" field. This field is required.

Street2:

Enter the second line of the street address for the PD/PI in the "Street2" field. This field is optional.

City:

Enter the City for address of the PD/PI. This field is required.

County/Parish:

Enter the county/parish for address of the PD/PI.

State:

Enter the State where the PD/PI is located. This field is required if the PD/PI is located in the United States.

Province:

Enter the province for PD/PI. If "Country" is not Canada, please leave blank

Country:

Select the country for the PD/PI address.

ZIP/Postal Code:

Enter the postal code (e.g., ZIP code) of the PD/PI. A nine-digit ZIP Code is required.

Phone Number:

Enter the daytime phone number for the PD/PI. This field is required.

Fax Number:

Enter the fax number for the PD/PL

E-mail:

Enter the e-mail address for the PD/PI. This field is required.

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Additional Instructions for Fellowship:

Provide the name of the individual Fellowship applicant (considered the PD/PI for F award programs). If the Fellowship applicant is not located at the applicant organization at the time the application is submitted, the information should reflect where the Fellowship applicant can be reached prior to the requested award start date. If the PD/PI is not located at the applicant organization at the time of submission, the Commons account for the PD/PI must be affiliated with the applicant organization. For additional information on creating affiliations for users in the eRA Commons, see: https://era.nih.gov/commons/commons-help/175.htm.

Multiple PD/PIs do not apply to fellowship applications.

15. Estimated Project Funding

a. Total Federal Funds Requested

Enter total Federal funds requested for the entire project period. This field is required.



Additional Instructions for Fellowship:

Applicants should refer to the NIH/OER Research Web site (https://researchtraining.nih.gov) for current stipend and other budgetary levels, and enter the total amount being requested for the entire period of support. This amount includes the applicable stipend amount, the actual tuition and fees, and the standard institutional allowance.

If new stipend or other payment levels for Kirschstein-NRSA fellowships are announced after the time of application, these amounts will be automatically adjusted at the time of award.

Extraordinary Costs. Additional funds may be requested by the institution when the training of a fellow involves extraordinary costs for travel to field sites remote from the sponsoring institution or accommodations for fellows who are disabled, as defined by the Americans with Disabilities Act. The funds requested for extraordinary costs must be reasonable in relationship to the total dollars awarded under a fellowship and must be directly related to the approved research training project. Such additional funds shall be provided only in exceptional circumstances that are fully justified and explained by the institution in the application or as part of a special written request.

b. Total Non-Federal Funds

For applications to NIH and other PHS agencies, enter "0" in this field unless cost sharing is a requirement for the specific announcement. This field is required.

c. Total Federal & Non-Federal Funds

For NIH and other PHS agencies applicants, this field will be the same as Total Federal Funds Requested above unless the specific announcement indicates that cost sharing is a requirement. This field is required.

d. Estimated Program Income

Identify any Program Income estimated for this project period, if applicable. This field is required.



Additional Instructions for Fellowship:

Not applicable to fellowships. Enter \$0.00.

16. Is Application Subject to Review by State Executive Order 12372 Process?

For NIH and other PHS agencies submissions using the SF424 (R&R), applicants should check "No, Program is not covered by E.O. 12372."

17. Certification

The list of NIH and other PHS agencies Assurances, Certifications, and other Policies is found in Supplemental Instructions, Part III.

The applicant organization is responsible for verifying its eligibility and the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application, including the Facilities and Administrative rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

Check "I agree" to provide the required certifications and assurances. This field is required.

18. SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation

If applicable, attach the SFLLL or other explanatory document per agency instructions.

If unable to certify compliance in with the Certification above attach an explanation. Additionally, as applicable, attach the SFLLL (Standard Form LLL, Disclosure of Lobbying Activities) or other documents in this item. A fillable version of the SFLLL form is available at http://www.whitehouse.gov/omb/assets/omb/grants/sflllin.pdf.

19. Authorized Representative

This is equivalent to the individual with the organizational authority to sign for an application; otherwise known as the Authorized Organization Representative or the Signing Official.

Prefix:

Enter the prefix (Mr., Mrs., Rev.) for the name of the Authorized Representative.

First Name:

Enter the first (given) name of the Authorized Representative. This field is required.

Middle Name:

Enter the middle name of the Authorized Representative.

Last Name:

Enter the last (family) name of the Authorized Representative. This field is required.

Suffix:

Enter the suffix (e.g., Jr., Sr., Ph.D.) for the Authorized Representative.

Position/Title:

Enter the Title of the name of the Authorized Representative. This field is required.

Organization Name:

Enter the name of the organization for the Authorized Representative. This field is required.

Department:

Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization of the Authorized Representative.

Division:

Enter the name of the primary organizational division, office, or major subdivision of the Authorized Representative.

Street1:

Enter the first line of the street address for the Authorized Representative in the "Street1" field. This field is required.

Street2:

Enter the second line of the street address for the Authorized Representative in the "Street2" field. This field is optional.

City:

City for address of the Authorized Representative. This field is required.

County/Parish:

Enter the county/parish for address of the Authorized Representative.

State:

Enter the State where the Authorized Representative is located. This field is required if the Authorized Representative is located in the United States.

Province:

Enter the province for the Authorized Representative. If "Country" is not Canada, please leave blank.

Country:

Select the country for the Authorized Representative address.

ZIP/Postal Code:

Enter Postal Code (e.g., ZIP code) of the Authorized Representative. This field is required if the Authorized Representative is located in the United States. A nine-digit Zip code is required.

Phone Number:

Enter the daytime phone number for the Authorized Representative. This field is required.

Fax Number:

Enter the fax number for the Authorized Representative.

E-mail:

Enter the e-mail address for the Authorized Representative. This field is required.

Signature of Authorized Representative:

It is the organization's responsibility to assure that only properly authorized individuals sign in this capacity and/or submit the application to Grants.gov. If this application is submitted through Grants.gov, leave blank. If a hard copy is submitted, the AOR must sign this block.

Date Signed:

If this application is submitted through Grants.gov, the system will generate this date. If submitting a hard copy, enter the date the AOR signed the application.

20. Pre-Application

Unless specifically noted in a Funding Opportunity Announcement, NIH and other PHS agencies do not use Pre-applications and this attachment field should not be used for any other purpose.

If submitting a pre-application, provide a summary description of the project in accordance with the announcement and/or agency specific instructions, and save the file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.



Additional Instructions for Fellowship:

Not applicable for fellowships. Leave blank.

21. Cover Letter Attachment

Attach the cover letter, addressed to the Division of Receipt and Referral, in accordance with the announcement and/or the agency specific instructions.

Applicants are encouraged to include a cover letter with the competing application. Please attach the cover letter in the correct location, **specifically verify that the cover letter has not been uploaded to the pre-application field which is directly above the cover letter field**. This will ensure the attachment is kept separate from the assembled application in Commons and only made available to appropriate staff.

A cover letter should not be included with post-award submissions such as administrative supplements, change of grantee institution, or successor-in-interest. The cover letter is only for internal use and will not be shared with peer reviewers. The letter should contain any of the following information that applies to the application:

- 1. Application title.
- 2. Funding Opportunity (PA or RFA) title of the NIH initiative.

- For late applications (see Late Application policy in http://grants.nih.gov/grants/funding/submissionpolicies.htm) include specific information about the timing and nature of the cause of the delay.
- 4. When submitting a Changed/Corrected Application after the due date, a cover letter is required explaining the reason for late submission of the Changed/Corrected Application. If you already submitted a cover letter with a previous submission and are now submitting a late Changed/Corrected Application, you must include all previous cover letter text in the revised cover letter attachment. The system does not retain any previously submitted cover letters; therefore, you must repeat all information previously submitted in the cover letter as well as any additional information.
- 5. Explanation of any subaward budget components that are not active for all periods of the proposed grant Section F.240 Senior/Key Person Profile (Expanded) Form.
- 6. Statement that you have attached any required agency approval documentation for the type of application submitted. This may include approval for applications \$500,000 or more, approval for Conference Grant or Cooperative Agreement (R13 or U13), etc. It is recommended that you include the official communication from an NIH official as part of your cover letter.
- 7. When intending to submit a video as part of the application, the cover letter must include information about the intent to submit it; if this is not done, a video will not be accepted. See NOT-OD-12-141 for additional information.
- Include a statement in the cover letter if the proposed studies will generate large-scale human or non-human genomic data as detailed in the NIH Genomic Data Sharing Policy (<u>NOT-OD-14-11</u> and <u>NOT-OD-15-027.</u>)

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Additional Instructions for Fellowship:

Individual fellowship applicants must include a cover letter that contains a list of Referees (including name, departmental affiliation, and institution). The cover letter is only for internal use and will not be shared with peer reviewers.

F.220 - R&R Other Project Information Form

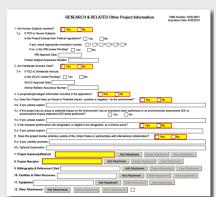
The Other Project Information Form is used for all grant applications. This form includes questions on the use of human subjects and vertebrate animals, as well as fields to upload an abstract, project narrative, references, equipment lists, and facilities descriptions.



Quick Links

- 1. Are Human Subjects Involved?
- 1a. If YES to Human Subjects
- 2. Are Vertebrate Animals Used?
- 2a. If YES to Vertebrate Animals
- 3. Is proprietary/privileged information included in the application?
- 4. Environmental Questions
- 5.

 | Is the research performance site designated, or eligible to be designated, as a historic place? Yes/No
 | Does this project involve activities outside of the
- 6. <u>United States or partnerships with International Collaborators?</u>
- 7. Project Summary/Abstract
- 8. Project Narrative
- 9. Bibliography & References Cited
- 10. Facilities & Other Resources
- 11. Equipment
- 12. Other Attachments



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Additional Instructions for Fellowship:

Note: This form should be completed in consultation with the Sponsor and Administrative Officials at the Sponsoring Institution

1. Are Human Subjects Involved?

If activities involving human subjects are planned at any time during the proposed project at any performance site, check yes. Check Yes even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If activities involving human subjects are not planned at any time

during the proposed project at any performance site, select no and skip the rest of block 1. This field is required.

Note that applications involving the use of human biospecimens or data may or may not be considered as research involving human subjects depending on the details of the materials to be used. Applications that involve the use of human materials that check No for human subjects involvement must provide a clear justification about why this use does not constitute human subjects research. For more detail, refer to Supplemental Instructions, Part II.

1.a. If YES to Human Subjects

Is the Project Exempt from Federal Regulations? Yes/No

Yes: If the project is exempt from Federal regulations, check Yes. If yes, check the appropriate exemption number.

No: If the project is not exempt from Federal regulations, check No.

If yes, check appropriate exemption number 1, 2, 3, 4, 5, 6:

Select the appropriate exemption number from 1, 2, 3, 4, 5, 6.

If human subject activities are exempt from Federal regulations, provide the exemption numbers corresponding to one or more of the exemption categories. The six categories of research that qualify for exemption from coverage by the regulations are defined in the Common Rule for the Protection of Human Subjects. These regulations can be found at http://www.hhs.gov/ohrp/humansubjects/quidance/45cfr46.html.

OHRP guidance states that appropriate use of Exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (http://answers.hhs.gov/ohrp/categories/1564). Institutions often designate their IRB to make this determination. Because NIH does not require IRB approval at the time of application, the exemptions designated often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review.

Proposed research may include more than one research project; thus the application may include individual projects that meet the requirements for non-exempt or exempt human subjects research, or are not defined as human subjects research. Human subjects research should be designated as exempt if all of the proposed research meets the criteria for one or more of the six exemptions.

If no, is the IRB review Pending? Yes/No

If IRB review is pending, check Yes. If IRB review is not pending, check No.

IRB Approval Date:

Enter the latest Institutional Review Board (IRB) approval date (if available). Leave blank if Pending.

Applicants should check "Yes" to the question "Is the IRB review Pending?" even if the IRB review/approval process has not yet begun at the time of submission. Also note that an IRB Approval Date is not required at the time of submission. This may be requested later in the pre-award cycle as a Supplemental Instructions, Part III Section 1.7 requirement.

Human Subject Assurance Number:

Enter the approved Federalwide Assurance (FWA) number that the applicant has on file with the Office for Human Research Protections. Enter the 8-digit number. Do not enter "FWA" before the number.

Insert "None" if the applicant organization does not have an approved FWA on file with OHRP. In this case, the applicant organization, by the signature in the Certification signature section on the SF424 (R&R) Cover form, is declaring that it will comply with 45 CFR part 46 and proceed to obtain a FWA (see http://www.hhs.gov/ohrp). Do not insert the FWA number of any collaborating institution in the space provided.

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Additional Instructions for Fellowship:

In many instances, the Fellow will be participating in research supported by research project grants for which the IRB review of human subjects is already complete or an exemption has been designated. This review or exemption designation is sufficient, provided that the IRB determines that participation of the Fellow does not substantially modify the research.

If the sponsoring institution has an approved FWA on file with OHRP that covers the specific activity, provide the number and the latest date of approval by the IRB of the proposed activities. This date must be no earlier than one year before the due date for which the application is submitted.

2. Are Vertebrate Animals Used?

If activities involving vertebrate animals are planned at any time during the proposed project at any performance site, check yes. If no, skip the rest of block 2. This field is required.

Note that the generation of custom antibodies constitutes an activity involving vertebrate animals. If animal involvement is anticipated within the period of award but plans are indefinite, check "Yes" and add the Vertebrate Animals attachment to provide an explanation and to indicate when it is anticipated that animals will be used. If an award is made prior to the involvement of animals, the grantee must provide all of the information required by adding a Vertebrate Animals attachment in the Research Plan and verifying an IACUC approval to the awarding component.



Additional Instructions for Fellowship:

If animal involvement is anticipated within the period of award but plans are indefinite, check "Yes" and add the PHS Fellowship Supplemental Form, Vertebrate Animals, attachment to provide an explanation and to indicate when it is anticipated that animals will be used. If an award is made prior to the involvement of animals, the grantee must provide all of the information required by adding a PHS Fellowship Supplemental Form, Vertebrate Animals, attachment in the Other Research Training Plan, and verifying an IACUC approval to the awarding component. See the PHS Fellowship Supplemental Form (Section F.430 - PHS Fellowship Supplemental Form) for a specific data item on "Indefinite Vertebrate Animal Use."

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending?

Indicate if an Institutional Animal Care and Use Committee (IACUC) review is pending.

Click Yes if an IACUC review is pending. Click No, if no review is pending. Check "Yes" even if the IACUC review and approval process has not yet begun.

IACUC Approval Date:

Enter the latest IACUC approval date (if available). Leave blank if Pending. IACUC approval must have been granted within three years to be valid. Note that an IACUC Approval Date is not required at the time of submission. NIH does not require verification of review and approval of the proposed research by the IACUC before peer review of the application. However, this information is required under Supplemental Instructions, Part III Section 1.7.

Animal Welfare Assurance Number

Enter the Federally approved assurance number, if available. Enter "None" if the applicant organization does not have an OLAW-approved Animal Welfare Assurance. To determine if the applicant organization holds an Animal Welfare Assurance, see the lists of Domestic and Foreign Assured institutions. Do not enter the Animal Welfare Assurance number for a Project/Performance Site of a collaborating institution. When an applicant organization does not have an Animal Welfare Assurance, the Authorized Organization Representative's signature on the application constitutes declaration that the applicant organization will submit an Animal Welfare Assurance when requested by OLAW. If the applicant organization has neither an animal care and use program, facilities to house animals and conduct research on site, nor an IACUC, and the animal work will be conducted at an institution with an Animal Welfare Assurance, the applicant must obtain an Inter-institutional Assurance from OLAW prior to an award.

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Additional Instructions for Fellowship:

Enter "None" if the applicant organization does not have an OLAW-approved Animal Welfare Assurance. To determine if the applicant organization holds an Animal Welfare Assurance, see the lists of Domestic and Foreign Assured institutions. Do not enter the Animal Welfare Assurance number for a Project/Performance Site of a collaborating institution. When an applicant organization does not have an Animal Welfare Assurance, the Authorized Organization Representative's signature on the application constitutes declaration that the applicant organization will submit an Animal Welfare Assurance when requested by OLAW.

In many instances, the Fellow will be participating in research supported by research project grants for which the IACUC review has been obtained. This review is sufficient, provided that participation of the Fellow does not substantially modify the research. The appropriate grant(s) must be identified along with the IACUC approval date(s).

The Sponsoring Institution must ensure that the Fellow is enrolled in the institution's animal welfare training and safety programs for personnel who have contact with animals, as appropriate. It is also the Sponsoring Institution's responsibility to ensure that the Fellow is properly supervised when working with live vertebrate animals.

Also see the instructions for the PHS Fellowship Supplemental Form for additional information (Section F.430 - PHS Fellowship Supplemental Form).

3. Is proprietary/privileged information included in the application?

Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, check yes and clearly mark each line or paragraph on the pages containing the proprietary/privileged information with a legend similar to: "The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation." This field is required.

If a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. Although the grantee institution and the PD/PI will be consulted about any such disclosure, the PHS will make the final determination. Any indication by the applicant that the application contains proprietary or privileged information does not automatically shield the information from release in response to a Freedom of Information Act (FOIA) request should the application result in an award (see 45 CFR Part 5). If an applicant fails to identify proprietary information at the time of submission as instructed in the application guide, a significant substantive justification will be required to withhold the information if requested under FOIA.

4. Environmental Questions

Most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment, and NIH has established several categorical exclusions allowing most applicants to answer 'No' to this question unless a specific FOA indicates that the National Environmental Policy Act (NEPA) applies. However, if an applicant expects that the proposed project will have an actual or potential impact on the environment, or if any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below, the box marked "Yes" should be checked and an explanation provided in field 4.b.

- 1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
- 2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.
- 3. Potential effects of the proposed research are unique or highly uncertain.
- 4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
- 5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous wasted, etc.)
- 6. The proposed research may have a possible impact on endangered or threatened species.
- 7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
- 8. The proposed research may introduce new sources of radiation or radioactive materials.
- 9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

4.a. Does this project have an actual or potential impact on the environment?

Indicate if this project has an actual or potential impact on the environment? Click No here if this is not the case. This field is required.

4.b. If yes, please explain

Explanation of the actual or potential impact on the environment.

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed?

Check yes or no. This field is required.

4.d. If yes, please explain

Enter additional details about the EA or EIS.

5. Is the research performance site designated, or eligible to be designated, as a historic place? Yes/No

If any research performance site is designated, or eligible to be designated, as a historic place, if Yes, check the Yes box and then provide an explanation in the box provided in 5.a. Otherwise, check the No box. This field is required.

5.a. If yes, please explain

If you checked the Yes box indicating any performance site is designated, or eligible to be designated, as a historic place, provide the explanation here.

6. Does this project involve activities outside of the United States or partnerships with International Collaborators?

Indicate whether this project involves activities outside of the United States or partnerships with international collaborators. Check yes or no. This field is required.

Applicants to NIH and other PHS agencies must check "Yes" if the applicant organization is a foreign institution or if the project includes a foreign component. For a definition of a foreign component, see "Definitions" section of Supplemental Instructions, Part III.

6.a. If yes, identify countries

Enter the countries with which international cooperative activities are involved.

6.b. Optional Explanation

Enter an explanation for involvement with outside entities (optional).

If you have checked "Yes" to 6, applicants to the NIH and other PHS agencies must describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), whether similar research is being done in the United States and whether there is a need for additional research in this area. Provide this information in a separate file, attaching it as Item 12, Other Attachments. In the body of the text, begin the section with a heading indicating "Foreign Justification." When saving this file, please name it "Foreign Justification" as well.



Additional Instructions for Fellowship:

If you have checked "Yes" to 6, applicants to the NIH and AHRQ must describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), including the reasons why the facilities, the mentor, or other aspects of the proposed experience are more appropriate than in a domestic setting. The justification is evaluated in terms of the scientific advantages of the foreign training experience as compared to the training available domestically.

7. Project Summary/Abstract

The Project Summary is meant to serve as a succinct and accurate description of the proposed work when separated from the application.

State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person. Finally, please make every effort to be succinct.

This section must be no longer than 30 lines of text, and follow the required <u>font and margin</u> <u>specifications</u>. An abstract which exceeds this allowable length may be flagged as an error by the agency upon submission. This would require a corrective action before the application will be accepted.

As noted above, do not include proprietary, confidential information or trade secrets in the description section. If the application is funded, the Project Description will be entered into an NIH database and made available on the NIH Research Portfolio Online Reporting Tool (RePORT, available at http://report.nih.gov) and will become public information.

The attachment must be in PDF format. (See <u>Formatting Attachments</u> for additional information on preparing attachments.)

8. Project Narrative

Provide Project Narrative in accordance with the announcement and/or agency-specific instructions. Please click the Add Attachment button to the right of this field to complete this entry.

For NIH and other PHS agencies applications, using no more than two or three sentences, describe the relevance of this research to public health. For example, NIH applicants can describe how, in the short or long term, the research would contribute to fundamental knowledge about the nature and behavior of living systems and/or the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. If the application is funded, this public health relevance statement will be combined with the project summary (above) and will become public information.

A separate Fellowship Supplemental form is required for NIH and other PHS agencies applications. Refer to Section F.430 - PHS Fellowship Supplemental Form, Research Plan for separate file uploads and instructions.

9. Bibliography & References Cited

Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. To attach a document for Bibliography and References Cited, click **Add Attachment**.

When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material). The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research

10. Facilities & Other Resources

No special form is required but this section must be completed and attached for submissions to NIH and other PHS agencies unless otherwise noted in an FOA. Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

For Early Stage Investigators (ESIs), describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI's project, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support. See http://grants.nih.gov/grants/new_investigators/.

If there are multiple performance sites, describe the resources available at each site.

Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about select agents must be described in the Research Plan, Select Agent Research.

Please click the **Add Attachment** button to the right of this field to complete this entry.



Additional Instructions for Fellowship:

Provide in the Attachment a detailed description of the institutional facilities and resources available to the Fellowship applicant. The information provided is of major

importance in establishing the feasibility of the goals of the fellowship training plan.

11. Equipment

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. Please click the **Add Attachment** button to the right of this field to complete this entry.

12. Other Attachments

Attach a file only to provide any other project information not provided above or in accordance with the announcement and/or agency-specific instruction.



Additional Instructions for Fellowship:

Certification Letter for Predoctoral Fellowships (F31) to Promote Diversity

Applications submitted for Individual Predoctoral Fellowships (F31) to Promote Diversity in Health-Related Research are required to attach a Certification Letter (titled Diversity_Eligibility_Ltr) from the institution certifying eligibility of the Fellowship applicant for the program. The letter should avoid revealing sensitive personal information, such as the candidate's specific racial/ethnic background or type of disability. The Certification Letter must be on institutional letterhead and scanned so that an institutional official signature is visible.

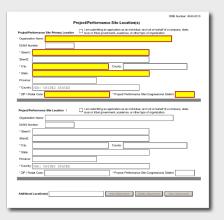
F.230 - Project/Performance Site Location (s) Form

The Project/Performance Site Location(s) Form is used for all grant applications. Indicate the primary site where the work will be performed. If a portion of the project will be performed at any other site(s), identify the site location (s) in the blocks provided.

View larger image

Quick Links

- 1. Project/Performance Site Primary Location
- 2. Project/Performance Site Location 1
- 3. Additional Performance Site Locations



Project/Performance Site Primary Location

Generally, the Primary Location should be that of the applicant organization or identified as off-site in accordance with the conditions of the applicant organization's negotiated Facilities and Administrative (F&A) agreement. This information must agree with the F&A information on the budget form of the application.

If there is more than one performance site, including any Department of Veterans Affairs (VA) facilities and foreign sites, list them in the fields provided for Location 1 - # below. Applicants should also provide an explanation of resources available from each Project/Performance Site on the Facilities and Resources attachment of the Section F.220 - R&R Other Project Information form.

Unless otherwise instructed in the FOA, do not check the "I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization" box.

Human Subjects:

If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under an appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR part 46 and other NIH human subject related policies described in Supplemental Instructions Part II of this Application Guide and in the NIH Grants Policy Statement.

Vertebrate Animals:

For research involving live vertebrate animals, the applicant organization must ensure that all Project/Performance Sites hold an OLAW-approved Animal Welfare Assurance. If the applicant organization has neither an animal care and use program, facilities to house animals and conduct research on site, nor an IACUC, and the animal work will be conducted at an institution with an

Animal Welfare Assurance, the applicant must obtain an Inter-institutional Assurance from OLAW prior to an award.

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Additional Instructions for Fellowship:

Indicate the primary site where the work will be performed. If a portion of the project will be performed at any other site(s), identify the site location(s) in the blocks provided.

One of the sites indicated must be the sponsoring organization; generally, the Primary Location should be that of the sponsoring organization. Indicate where the training described in the Research Training Plan will be conducted. If there is more than one training site, including any Department of Veterans Affairs (VA) facilities or foreign sites, list them all in the fields provided for Location 1, and additional locations, as necessary.

If there are unusual circumstances involved in the research training proposed, such as fieldwork or a degree sought from an institution other than the one in which the research training will take place, describe these circumstances in Section F.220 - R&R Other Project Information Form, Facilities and Resources.

Foreign Sponsorship: An individual may request support for training abroad. In such cases, the applicant is required to provide detailed justification for the foreign training, including the reasons why the facilities, the mentor, or other aspects of the proposed experience are more appropriate than in a domestic setting. The justification is evaluated in terms of the scientific advantages of the foreign training as compared to the training available domestically. Foreign training will be considered for funding only when the scientific advantages are clear. The foreign justification should be provided as a separate attachment in Section F.220 - R&R Other Project Information Form, Item 12

Organization Name:

Indicate the organization name of the primary site where the work will be performed. If a portion of the project will be performed at any other sites(s), identify the site location(s) in the block(s) provided.

DUNS Number:

Enter the DUNS number associated with the organization where the project will be performed. The DUNS Number is a required field for the Primary Performance Site.

Street1:

Enter first line of the street address of the primary performance site location. This field is required.

Street2:

Enter second line of the street address of the primary performance site location, if applicable.

City:

Enter the city for address of the primary performance site location. This field is required.

County/Parish:

Enter the County or parish of the primary performance site location.

State:

Enter the State where the primary performance site location is located. This field is required if the Project Performance Site is located in the United States.

Province:

Enter the province for the primary performance site location. If "Country" is not Canada, please leave blank.

Country:

Select the Country of the Primary Performance Site location. This field is required.

ZIP Code:

Enter the nine-digit postal code (e.g., ZIP code) of the performance site location. This field is required if the performance site location is in the United States. A nine-digit Zip code is required.

Project/Performance Site Congressional District:

Enter the Congressional District in the format: 2 character State Abbreviation - 3 character District Number. Examples: CA-005 for California's 5th district, CA-012 for California's 12th district.

If all districts in a state are affected, enter "all" for the district number. Example MD-all for all congressional districts in Maryland.

If nationwide (all districts in all states), enter US-all.

If the program/project is outside the U.S., enter 00-000.

To locate your congressional district, visit the Grants.gov Web site. Note it is likely this field will be identical to the "Congressional District of Applicant" field provided elsewhere in the application.

For States and U.S. territories with only a single congressional district enter "001" for the district code. For jurisdictions with no representative, enter "099". For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098, PR-098.

Project/Performance Site Location 1

Organization Name:

Enter the name of organization of the performance site location. If a portion of the project will be performed at any other sites(s), identify the site location(s) in the block(s) provided.

DUNS Number:

Enter the DUNS number associated with the organization where the project will be performed. This field is optional.

Street1:

Enter first line of the street address for the performance site location in the "Street1" field. This field is required.

Street2:

Enter the second line of the street address for the performance site location in the "Street2" field. This field is optional.

City:

Enter the city of the performance site location. This field is required.

County:

Enter the county of the performance site location.

State:

Enter the State where the primary performance site location is located. This field is required if the Project Performance Site is located in the United States.

Province:

Enter the province where the primary performance site location is located. If "Country" is not Canada, please leave blank.

Country:

Select the country for the performance site location. This field is required.

ZIP Code:

Enter the nine-digit postal code (e.g., ZIP code) of the performance site location. This field is required if the performance site location is in the United States.

Project/Performance Site Congressional District:

Enter the Congressional District in the format: 2 character State Abbreviation - 3 character District Number. Examples: CA-005 for California's 5th district, CA-012 for California's 12th district.

If all districts in a state are affected, enter "all" for the district number. Example MD-all for all congressional districts in Maryland.

If nationwide (all districts in all states), enter US-all.

If the program/project is outside the U.S., enter 00-000.

To locate your congressional district, visit the Grants.gov Web site. Note it is likely this field will be identical to the "Congressional District of Applicant" field provided elsewhere in the application.

For States and U.S. territories with only a single congressional district enter "001" for the district code. For jurisdictions with no representative, enter "099". For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098, PR-098.

Additional Performance Site Locations

For additional performance site locations, click Next Site to display the fields for Project/Performance Site Locations 2 through 300.

If you need to add more than 300 locations, enter the information in a separate file. In the Additional Locations section at the bottom of the form, click Add Attachment, select the file, and then click Open. A sample Additional Performance Sites format page for greater than eight locations can be found at http://grants.nih.gov/grants/forms/additional-performance-site.htm.

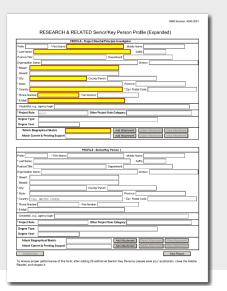
F.240 - R&R Senior/Key Person Profile (Expanded) Form

The Senior/Key Person Profile (Expanded) Form is used for all grant applications, and allows the collection of data for all senior/key persons associated with the project. The information for the PD/PI is pre-populated from the SF424 (R&R) form. See instructions in Section F.200 - SF 424 (R&R) Form if these fields are empty.



Quick Links

- Profile Project Director/Principal Investigator (PD/PI)
- Instructions for a Biographical Sketch
- Profile Senior/Key Person
- Additional Senior/Key Person Profile(s)



Profile - Project Director/Principal Investigator (PD/PI)

Unless otherwise specified in an agency announcement, senior/key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included if they meet this definition.

Data must be entered for the first 100 individuals (PD/PI + 99 others) before the Additional Senior/Key Person Form Attachments section becomes available.



Additional Instructions for Fellowship:

Starting with the PD/PI (Fellowship applicant), provide a profile for each senior/key person proposed.

Note that agency policies concerning "Multiple PD/PIs" are not applicable to F applications. Therefore, do not use the PD/PI role for any other senior/key personnel.

Prefix:

Pre-populated from the SF 424 (R&R). The prefix (e.g., Mr., Mrs., Rev.) for the name of the PD/PI

First Name:

Pre-populated from the SF 424 (R&R). The first (given) name of the PD/PI. This field is required.

Middle Name:

Pre-populated from the SF 424 (R&R). The middle name of the PD/PI.

Last Name:

Pre-populated from the SF 424 (R&R). The last (family) name of the PD/PI. This field is required.

Suffix:

Pre-populated from the SF 424 (R&R). The suffix (e.g., Jr, Sr, PhD) for the name of the PD/PI.

Position/Title:

Pre-populated from the SF 424 (R&R). The title of the PD/PI.

Department:

Pre-populated from the SF 424 (R&R). The name of primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.

Organization Name:

Pre-populated from the SF 424 (R&R). The name of organization of the PD/PI.

Division:

Pre-populated from the SF 424 (R&R). The name of primary organizational division, office, or major subdivision of the PD/PL

Street1:

Pre-populated from the SF 424 (R&R). The first line of the street address for the PD/PI in the "Street 1" field. This field is required.

Street2:

Pre-populated from the SF 424 (R&R). The second line of the street address for the PD/PI in the "Street 2" field. This field is optional

City:

Pre-populated from the SF 424 (R&R). The city for address of PD/PI. This field is required.

County/Parish:

Pre-Populated from the DF 424 (R&R). The county/parish for address of PD/PI.

State:

Pre-populated from the SF 424 (R&R). The state where the PD/PI is located. This field is required if the PD/PI is located in the United States.

Province:

Pre-populated from the SF 424 (R&R). The Province where the PD/PI is located. If "Country" is not Canada, this will be blank.

Country:

Pre-populated from the SF 424 (R&R). The country for the PD/PI address. This field is required.

ZIP Code:

Pre-populated from the SF 424 (R&R). The postal Code (e.g., ZIP code) of PD/PI. This field is required if the PD/PI is located in the United States. A nine-digit Zip code is required.

Phone Number:

Pre-populated from the SF 424 (R&R). The daytime phone number for the PD/PI. This field is required.

Fax Number:

Pre-populated from the SF 424 (R&R). The fax number for the PD/PI.

E-mail:

Pre-populated from the SF 424 (R&R). The e-mail address for the PD/PI. This field is required for PD/PI.

Credential, e.g., agency login:

For NIH and other PHS agencies, registration in the eRA Commons for all PD/PIs is required. The assigned Commons username (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here and must have the PI role in eRA Commons. This is a required field for applications submitted to NIH and other PHS agencies. Applications will not pass agency validation requirements without this field.

Note for applications reflecting Multiple PD/PIs, the Commons username must be provided for all individuals assigned the PD/PI Role on the application.

Project Role:

Select PD/PI for this person.

Other Project Role Category:

Complete if you selected "Other Professional" or "Other" as a project role; e.g., Engineer, Chemist.

Degree Type:

Enter the highest academic or professional degree or other credentials (e.g., R.N.). This is optional information.

Degree Year:

Enter the year the highest degree or other credential was obtained. This is optional information.

Attach Biographical Sketch

See instructions below

Attach Current & Pending Support:

Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, you will be instructed to refer to Supplemental Instructions, Part III Section 1.8.

Instructions for a Biographical Sketch

Please note that these instructions apply to Research (R), Career Development (K), Training (T), Fellowship (F), Multi-Project (M) and SBIR/STTR (B).

- Include biographical sketches of all senior/key personnel and Other Significant Contributors.
- Use the sample format on the <u>Biographical Sketch Format Page</u> to prepare this section for all (modular and other) grant applications.
- The Biographical Sketch may not exceed five pages per person. This five-page limit includes the table at the top of the first page.
- Complete the education block at the top of the format page beginning with the baccalaureate or other initial professional education, such as nursing. Include postdoctoral training, separately referencing residency and clinical fellowship training, if applicable.

eRA Commons User Name

If the individual is registered in the eRA Commons, include the Commons User Name. This data item is required for the PD/PI (including fellowship applicants), primary sponsors of fellowship applicants, and all mentors of candidates for mentored career development awards. Commons User Name is optional for other project personnel. In other federal forms this information is referred to as "Credential, e.g., agency login." For information on the eRA Commons, see https://commons.era.nih.gov/commons/index.jsp.

Education

Complete the education block at the top of the format page beginning with the baccalaureate or other initial professional education, such as nursing. Include postdoctoral training, separately referencing residency and clinical fellowship training, if applicable. For each entry provide:

- the name and location of the institution
- the degree received (if applicable) and the month and year of entry and completion (or expected completion)
- the field of study (for residency entries the field of study should reflect the area of residency training)

Following the education block, complete Sections A, B, C, and D as described below.

A. Personal Statement

Briefly describe why you are well-suited for your role(s) in this project. The relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and/or your past performance in this or related fields. Note the following additional instructions:

- For institutional research training, institutional career development, or research education
 grant applications, faculty who are not senior/key persons are encouraged to complete this
 section, but not required to do so.
- Applicants for dissertation research awards should include a description of their career goals
 and intended career trajectory and their interest in the specific areas of research designated
 in the FOA, in addition to the information outlined above.
- Candidates for Research Supplements to Promote Diversity in Health-Related Research should include a description of their general scientific achievements and/or interests, as well as specific research objectives and career goals, in addition to the information outlined above. Indicate any current source(s) of educational funding.
- If there are factors affecting your past productivity that you wish to explain, such as family
 care responsibilities, illness, disability, or military service, you may address them in your
 personal statement.
- Indicate if you have published or created research products under another name.
- You may mention specific contributions to science that are not included in Section C. Do not
 present or expand on materials that should be described in other sections of this biosketch
 or the application.
- Figures, tables and graphics are not allowed.

You may cite up to four publications or research products that highlight your experience and qualifications for this project. Research products can include audio or video products; conference proceedings such as meeting abstracts, posters or other presentations; patents;

data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

B. Positions and Honors

List in chronological order positions held since the completion of your most recent degree, concluding with your present position. High school students and undergraduates may include any previous positions. For individuals, such as fellowship applicants or career development award candidates, who are not currently located at the applicant organization, include the expected position at the applicant organization, with the expected start date.

List any relevant academic and professional achievements and honors. In particular:

- Students, postdoctorates, and junior faculty should include scholarships, traineeships, fellowships, and development awards, as applicable.
- Clinicians should include information on clinical licensure and specialty board certification, if applicable.
- Include present membership on any Federal Government public advisory committee.

C. Contributions to Science

Candidates for Research Supplements to Promote Diversity in Health-Related Research who are high school students, undergraduates, and postbaccalaureates are not required to complete this section.

Briefly describe up to five of your most significant contributions to science. While all applicants may describe up to five contributions, graduate students and postdoctorates are encouraged to consider highlighting two or three they consider most significant. Descriptions may include a mention of research products under development, such as manuscripts that have not yet been accepted for publication.

Each contribution should be no longer than one half page, including citations. These contributions do not have to be related to this project. For each contribution:

- Indicate the historical background that frames the scientific problem; the central finding(s);
 the influence of the finding(s) on the progress of science or the application of those finding(s)
 to health or technology; and your specific role in the described work.
- You may cite up to four papers accepted for publication or research products that are relevant to the contribution.
 - Research products can include audio or video products; conference proceedings such as meeting abstracts, posters or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.
 - These citations do not have to be authored by you.

You may provide a URL to a full list of your published work. This URL must be to a Federal Government website (a .gov suffix). NIH recommends using My Bibliography. Providing a URL to a list of published work is not required, and reviewers are not required to look at the list.

D. Additional Information: Research Support and/or Scholastic Performance

Note the following instructions for specific types of applicants/candidates:

- High school students are not required to complete this section.
- Applicants for predoctoral and postdoctoral fellowships, dissertation research grants, and
 candidates for Research Supplements to Promote Diversity in Health-Related Research
 from the undergraduate through postdoctoral levels should use this section to provide
 information about their scholastic performance, following the instructions below. In
 situations where applicants/candidates in these categories also have research support, they
 should complete both parts of this section.

Research Support

For all other individuals required to complete a biosketch, list selected ongoing and completed research projects for the past three years (Federal or non-Federal support). Briefly indicate the overall goals of the projects and your responsibilities. Do not include number of person months or direct costs.

Do not confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are very different.

- As part of the biosketch section of the application, "Research Support" highlights your
 accomplishments, and those of your colleagues, as scientists. This information will be used
 by the reviewers in the assessment of each individual's qualifications for a specific role in
 the proposed project, as well as to evaluate the overall qualifications of the research team.
- In contrast, "Other Support" information is required for all applications that are selected to receive grant awards. NIH staff will request complete and up-to-date "other support" information from you after peer review.

Scholastic Performance

Predoctoral applicants/candidates (including undergraduates and postbaccalaureates): List by institution and year all undergraduate and graduate courses, with grades. In addition, in the space following the chart, explain any grading system if other than 1-100, A, B, C, D, F, or 0-4.0. Show levels required for a passing grade.

Postdoctoral applicants: List by institution and year all undergraduate courses and graduate scientific and/or professional courses germane to the training sought under this award, with grades. In the space following the chart, explain any grading system if other than 1-100, A, B, C, D, F, or 0-4.0. Show levels required for a passing grade.

Profile - Senior/Key Person

The remaining senior/key person profiles should be listed in alphabetical order. While alphabetical order is preferred, it is not required. However, be aware that these profiles will appear in the application in the order provided by the applicant. Therefore, peer reviewers will see them in the order presented. Those with a postdoctoral role should be included if they meet the definition of senior/key personnel.

Also use this section to list any Other Significant Contributors (OSCs), who are those individuals who commit to contribute to the scientific development or execution of the project, but do not commit any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at effort of "zero person months" or "as needed." Individuals with measurable effort may

not be listed as Other Significant Contributors (OSCs). Consultants should be included if they meet the OSC definition. OSCs should be listed **after** all senior/key persons.

A biosketch, including Research Support information, is required for all senior/key persons and OSCs as this highlights their accomplishments as scientists. Reviewers use these pages to address the "investigator" review criterion. However, if an award is to be made, Other Support information will not be required or accepted for OSCs since considerations of overlap do not apply to these individuals.

Should the level of involvement change for an individual listed as an OSC, requiring measurable effort on the award, the individual should be redesignated as "senior/key personnel." This change should be made before any compensation is charged to the project.

After providing data for each individual senior/key person (the following instructions also apply to OSCs), click the **Next Person** button at the bottom of the form to enter data for the next senior/key person. Continue in this manner until data has been provided for up to 100 senior/key persons. To ensure proper performance of this form, after adding 20 additional senior/key persons please save your application, close the Adobe reader, and reopen it. For applications involving more than 100 senior/key persons, the "Additional Senior/Key Person Profiles" fields will become available once data for the first 100 senior/key persons has been provided.

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Additional Instructions for Fellowship:

Fellowship awards require a primary sponsor, and there may be co-sponsor(s), consultants and contributors. All individuals who have committed to contribute to the scientific development and execution of the project, including sponsor and co-sponsors, should be identified as senior/key personnel, even if they are not committing any specified measurable effort to the proposed project. Sponsors and co-sponsors should be assigned the Project Role of "Other Professional" and then enter "Sponsor" or "Co-Sponsor" in the Other Project Role Category field.

Consultants should also be assigned the "Other Professional" role even if they are not committing any specified measurable effort. Then, enter the specific project role under "Other Project Role Category."

Any individuals identified as senior/key personnel who are committing specified measurable effort should be appropriately assigned under Project Role (and Other Project Role Category, if necessary).

Prefix:

Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of the Senior/Key Person.

First Name:

Enter the first (given) name of the Senior/Key Person. This field is required.

Middle Name:

Enter the middle name of the Senior/Key Person, if applicable.

Last Name:

Enter the last (family) name of the Senior/Key Person. This field is required.

Suffix:

Enter the suffix (e.g., Jr., Sr., Ph.D.) for the name of the Senior/Key Person.

Position/Title:

Enter the title of the Senior/Key Person.

Department:

Enter the name of primary organizational department, service, laboratory, or equivalent level within the organization of the Senior/Key Person.

Organization Name:

Enter the name of organization of the Senior/Key Person. This is a required field for applications submitted to NIH and other PHS agencies.

Division:

Enter the name of primary organizational division, office, or major subdivision of the Senior/Key Person.

Street1:

Enter first line of the street address for the Senior/Key Person in the "Street 1" field. This field is required.

Street2:

Enter second line of the street address for the Senior/Key Person in the "Street 2" field. This field is optional.

City:

City for address of Senior/Key Person. This field is required.

County/Parish:

County/Parish for address of Senior/Key Person.

State:

Enter the State where the Senior/Key Person is located. This field is required if the senior/key person is located in the United States.

Province:

Enter the Province where the Senior/Key Person is located. If "Country" is not Canada, please leave blank.

Country:

Select the country for the Senior/Key Person address. This field is required.

ZIP Code:

Enter the Postal Code (e.g., ZIP code) of Senior/Key Person. This field is required if the Senior/Key Person is located in the United States. A nine-digit Zip code is required.

Phone Number:

Enter the daytime telephone number for the Senior/Key Person. This field is required.

Fax Number:

Enter the fax number for the Senior/Key Person.

E-mail:

Enter the e-mail address for the Senior/Key Person. This field is required for the Senior/Key Person.

Credential, e.g., agency login:

If you are submitting to an agency (e.g., NIH) where you have an established personal profile, enter the agency ID. If not, leave blank.



Additional Instructions for Fellowship:

Fellowship Sponsors must provide a Commons username (See NOT-OD-14-129).

Project Role:

Select one. Use "Other" if a category is not listed in the pick list.

For applications reflecting Multiple PD/PIs, all such individuals must be assigned the PD/PI role, even those at organizations other than the applicant organization. The role of "Co-PD/PI" is not currently used by NIH and other PHS agencies. Assigning an individual(s) the role of "Co-PD/PI" will not identify the application as a Multiple PD/PI application. If applicants wish to use a different role, select "Other" for the Project Role field and then insert the appropriate role descriptor in the Other Project Role Category field.

If including individuals classified as "Other Significant Contributors (OSCs)," use the "Other" category and indicate "Other Significant Contributor" as the role in the "Other Project Role Category." OSCs should be listed last after all other senior/key persons have been listed.



Additional Instructions for Fellowship:

Sponsors, Co-sponsors and doctoral dissertation advisors should use the "Other" category and indicate the appropriate role (e.g. Sponsor) as the role in the "Other Project Role Category."

Other Project Role Category:

Complete if you selected "Other Professional" or "Other" as a project role; e.g., Engineer, Chemist.

Degree Type:

Enter the highest academic or professional degree or other credentials (e.g., R.N.). This is optional information.

Degree Year:

Enter the year the highest degree or other credential was obtained. This is optional information. Applicants should ensure that their degree information is current in their Commons Profile.

Attach Biographical Sketch:

Provide a biographical sketch for each senior/key person. Biographical sketches must follow the format described above.

Attach Current & Pending Support:

Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs refer to Supplemental Instructions, Part III Section 1.8.

Additional Senior/Key Person Profile(s)

If more than 99 senior/key person profiles are proposed, enter the information in a separate file and attach it here. A sample Additional Senior/Key Person Profiles format page for greater than 100 profiles can be found at: http://grants.nih.gov/grants/forms/additional-senior-key-person-profile.htm.

Additional Biographical Sketch(es) (Senior/Key Person):

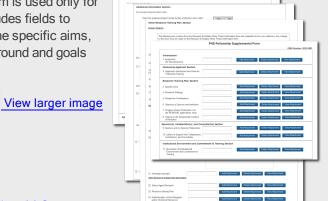
Provide a biographical sketch for each senior/key person. Biographical sketches must follow the format described above.

Additional Current and Pending Support(s):

Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, refer to Supplemental Instructions, Part III Section 1.8.

F.430 - PHS Fellowship Supplemental Form

The PHS Fellowship Supplemental Form is used only for Fellowship applications. This form includes fields to upload several attachments including the specific aims, research strategy, and applicant background and goals section.



Quick Links

- Introduction (if Applicable)
- Fellowship Applicant Section
- Research Training Plan Section
- Sponsor(s), Collaborator(s), and Consultant(s) Section
- Institutional Environment and Commitment to Training
- Section
- Other Research Training Plan Section
- Other Research Training Plan Information
- Additional Information Section
- Budget Section
- Appendix

It is strongly recommended that fellowship applicants and sponsors speak with a PHS Program Official for Institute or Center (IC)-specific guidance before preparing this application. These contacts are identified in tables associated with each FOA. In addition, a list of contacts specifically for extramural training at the NIH ICs can be found at https://researchtraining.nih.gov/tac-roster. For AHRQ, see https://www.ahrq.gov/funding/training-grants/contacts.html. Individuals always are encouraged to check these Web sites for the most current contact information.

The PHS Fellowship Supplemental Form should include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies. This section should be well-formulated and presented in sufficient detail that it can be evaluated for both its research training potential and scientific merit. It is important that it be developed in collaboration with your sponsor, but it should be written by you, the fellowship applicant.

Applicants must follow all policies and requirements related to proprietary information, page limits and formatting. See the following pages for more information:

- Proprietary Information: Sections 2.3.11.2 and 2.3.11.2.2 of the NIH Grants Policy Statement
- Page Limits: http://grants.nih.gov/grants/forms_page_limits.htm

• Formatting Attachments: http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm

Introduction (if Applicable)

1. Introduction to Application (Resubmission Only):

NIH policy allows a thirty-seven month window for resubmissions (A1 applications). The NIH will not accept a resubmission (A1) application that is submitted later than 37 months after submission of the new (A0) application that it follows. See NIH Notice NOT-OD-12-128 and NOT-OD-14-074 for additional information/clarification of NIH policy.

Required only if Type of Application is Resubmission. See specific instructions on the content of the introduction at http://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/type-of-application-submission.htm. First time (new) applications should not include an Introduction unless specified in the FOA.

The Introduction is a required attachment for Resubmissions and Revisions. Follow the page limits for the Introduction in the Table of Page limits at http://grants.nih.gov/grants/forms_page_limits.htm unless otherwise specified in the FOA.

Attach this information as a PDF file.

Fellowship Applicant Section

2. Applicant's Background and Goals for Fellowship Training:

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

A. Doctoral Dissertation and Research Experience:

Summarize your research experience in chronological order. Advanced graduate students, who have (or will have) completed their comprehensive examinations by the time of award, must also include a narrative of their doctoral dissertation (may be preliminary). If you have no research experience, list other scientific experience. Do not list academic courses. In summarizing their research experience, Postdoctoral and Senior Fellowship applicants should include the areas studied and conclusions drawn. Postdoctoral fellowship applicants should also specify which areas of research were part of their thesis or dissertation and which, if any, were part of a previous postdoctoral project.

B. Training Goals and Objectives:

Describe your overall training goals for the duration of the fellowship, and explain how the proposed fellowship will enable the attainment of these goals. Identify the skills, theories, conceptual approaches, etc. to be learned or enhanced during the award. As applicable, discuss how the proposed research will facilitate your transition to the next career stage.

C. Activities Planned Under this Award:

Describe, by year, the activities (research, coursework, etc.) you will be involved in during the proposed award and estimate the percentage of time to be devoted to each activity, based on a normal working day for a full-time fellow as defined by the sponsoring institution; the percentage should total 100 for each year. The activities planned under this award should be individually tailored and well integrated with your research project. Describe the skills and techniques that you intend to learn as well as any planned, non-research activities (e.g. those relating to professional development and clinical activities) during the award period. Provide a timeline detailing the proposed research training and related activities for the entire duration of the program

Attach this information as a PDF file.

Research Training Plan Section

A Research Training Plan is required for all types of individual F awards. The Research Training Plan is a major part of the Fellowship award plan. It is important to relate the research to the applicant's scientific career goals. Describe how the research, coupled with related training activities, will provide the experience, knowledge, and skills necessary to achieve the stated objectives of the Fellowship award. Explain the relationship between the applicant's research on the Fellowship award and the mentor's ongoing research program.

For most types of research, the plan should include: a specific hypothesis; a list of the specific aims and objectives that will be used to examine the hypothesis; a description of the methods/approaches/techniques to be used in each aim; a discussion of possible problems and how they will be managed; and, when appropriate, alternative approaches that might be tried if the initial approaches do not work.

The Research Training Plan of a Fellowship award is expected to be appropriate for, and tailored to the experience level of the applicant, and allow him/her to develop the skills needed for further career advancement; reviewers will evaluate the plan accordingly. The plan should be achievable within the requested time period. Pilot or preliminary studies and routine data gathering are generally not appropriate as the focus of a Fellowship award research training plan. Although applicants for Fellowship awards are expected to write the Research Training Plan, the mentor should review a draft of the plan and discuss it in detail with the applicant. Review by other knowledgeable colleagues is also helpful. Although it is understood that Fellowship applications do not require the extensive detail usually incorporated into regular research grant applications, a fundamentally sound Research Training Plan should be provided.

3. Specific Aims

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

State precisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Attach this information as a PDF file.

4. Research Strategy

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

Organize the Research Strategy section using the instructions provided below as guidance. Cite published experimental details within the text and provide the full reference in <u>Section F.220 - R&R Other Project Information Form</u>, Bibliography and References Cited.

A. Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

B. Innovation

 Fellowship applications should not include an Innovation section unless specified in the FOA.

C. Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 23 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in Item 22, below.
- If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.

If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.

As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.

Preliminary Studies for New Applications:

For new applications, include information on preliminary studies (including data collected by others in the lab), if any. Discuss the applicant's preliminary studies, data and/or experience pertinent to this application.

Progress Report for Renewal Applications:

Renewal applications for individual fellowships are rare. You should consult with your program official before preparing such an application. In the rare instance that you are submitting a renewal application, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes resulting from significant budget reductions. For any studies meeting the NIH definition for clinical research, discuss previous participant enrollment (e.g., recruitment, retention, inclusion of women, minorities, children etc.) as part of the progress report, particularly if relevant to studies proposed in the renewal or revision application. You should not submit a PHS Inclusion Enrollment Report form unless the enrollment is part of new or ongoing studies in the renewal application. A list of publications, manuscripts accepted for publication, patents, and other printed materials should be included in the Progress Report Publication List); do not include that information here.

Attach this information as a PDF file.

5. Respective Contributions

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

Describe the collaborative process between you and your sponsor/co-sponsor in the development, review, and editing of this research training plan. Discuss the respective roles in accomplishing the proposed research.

Attach this information as a PDF file.

6. Selection of Sponsor and Institution

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

Describe the rationale/justification for the selection of the sponsor and institution.

- Explain why the sponsor, co-sponsor (if any), and institution were selected to accomplish the
 research training goals. If the proposed research training is to take place at a site other than
 the sponsoring organization, provide an explanation here.
- Doctorate or Current Institution. (For postdoctoral and senior fellows only) Since training is
 expected to broaden a fellow's perspective, postdoctoral fellowship applicants requesting
 training at either their doctorate institution or at the institution where they have been training for
 more than a year must explain why further training at that institution would be valuable.

- Individuals applying for Senior Fellowships who are requesting training at the institution at which they are employed should provide a similar explanation.
- 3. Foreign Institution. If you are proposing a research training experience at a foreign institution, show that the foreign institution and sponsor offer special opportunities for training that are not currently available in the United States. Key factors in the selection of a foreign institution should be described. If applicable, the need for and level of proficiency in reading, speaking, and comprehending the foreign language should be addressed.

Attach this information as a PDF file.

7. Progress Report Publication List (for RENEWAL applications only)

In the rare instance that you are submitting a renewal application, list the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively.

For NIH applications only, when citing articles that fall under the NIH Public Access Policy, http://publicaccess.nih.gov/, were authored or co-authored by the fellowship applicant and arose from NIH support or arose from AHRQ funding provided after 2/19/16 (see http://grants.nih.gov/grants/guide/notice-files/NOT-HS-16-008.html), or arose from AHRQ support after the publication date of the AHRQ public access policy, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

Citations that are not covered by the NIH Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of these publications are not accepted as appendix material, see F. Appendix below).

Attach this information as a PDF file.

8. Training in Responsible Conduct of Research

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. See Supplemental Instructions Supplemental Instructions, Part III 1.16 for information on the NIH Policy on Training in the Responsible Conduct of Research (RCR).

The plan must address the five, required instructional components outlined in the NIH policy:

- 1. Format the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable);
- 2. Subject Matter the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics;

- 3. Faculty Participation the role of the mentor(s) and other faculty involvement in the instruction;
- 4. Duration of Instruction the total number of contact hours of instruction; and
- 5. Frequency of Instruction instruction must occur during each career stage and at least once every four years.

Document any prior instruction during the applicant's current career stage, including the inclusive dates instruction was last completed. See also NOT-OD-10-019.

Senior fellows may fulfill the requirement for instruction in responsible conduct of research by participating as lecturers and discussion leaders.

Attach this information as a PDF file.

Sponsor(s), Collaborator(s), And Consultant(s) Section

9. Sponsor and Co-Sponsor Statements

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA

Create a heading at the top of the first page titled "Section II--Sponsor and Co-Sponsor Statements."

Complete these items as comprehensively as possible so that a meaningful evaluation of the training environment can be made by the reviewers.

A. Research Support Available

In a table, list all current and pending research and research training support specifically available to the applicant for this particular training experience. Include funding source, complete identifying number, title of the research or training program, and name of the principal investigator, dates, and amount of the award. If the sponsor's research support will end prior to the end of the proposed training period, the sponsor should provide a contingency plan for how the fellow's research will be supported. Include this information for any co-sponsor as well.

The role of the sponsor in the integrated research and training plan should be described. If a sponsor team is proposed, this plan should describe the role of each sponsor and how they will communicate and coordinate their efforts to mentor the applicant effectively.

B. Sponsor's/Co-Sponsor's Previous Fellows/Trainees

Give the total number of predoctoral and postdoctoral individuals previously sponsored. Select up to five that are representative and, for those five, provide information on time spent in the lab their present employing organizations and position titles or occupations. Include this information for any co-sponsor as well.

C. Training Plan, Environment, Research Facilities

Describe the research training plan that you have developed specifically for the Fellowship applicant. The training plan should be individualized for the applicant, keeping in mind the candidate's strengths and any gaps in needed skills, and should be designed to enhance both research and clinical training (if applicable). Include items such as classes, seminars,

opportunities for interaction with other groups and scientists and any professional skills development opportunities. Describe the research environment and available research facilities and equipment. Indicate the relationship of the proposed research training to the applicant's career goals. Describe the skills and techniques that the applicant will learn. Relate these to the applicant's career goals. This information should be coordinated with information provided under Description of Institutional Environment and Commitment to Training.

For F30 applicants, the training plan should also provide opportunities to integrate clinical experiences during the research training component; a smooth transition to the clinical training component; and should have the potential to facilitate the applicant's transition to a residency or other program appropriate for his/her career goals, as applicable for the proposed clinical specialty.

For F31, F32, F33 applicants, the training plan should facilitate the applicant's transition to the next stage of his/her career.

D. Number of Fellows/Trainees to be Supervised During the Fellowship

Indicate whether pre- or postdoctoral. Include this information for any co-sponsor as well.

E. Applicant's Qualifications and Potential for a Research Career

Describe how the Fellowship applicant is suited for this research training opportunity based on his/her academic record and research experience level, including how the research training plan, and your own expertise as the sponsor will assist in producing an independent researcher.

10. Letters of Support from Collaborators, Contributors, and Consultants

Attachments may be provided (if applicable) by collaborators, consultants, advisors, etc. Relevant information applicable to the fellow's planned research training and future goals may be provided by any contributor or advisor via an attachment.

Institutional Environment And Commitment To Training Section

11. Description of Institutional Environment and Commitment to Training

This attachment is required. Follow the page limits for Fellowship Applications in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

The sponsoring institution must document a strong, well-established research program related to the candidate's area of interest, including the names of key faculty members relevant to the candidate's proposed developmental plan. Referring to the resources description (Section F.220 - R&R Other Project Information Form, Facilities and Other Resources), indicate how the necessary facilities and other resources will be made available for career enhancement as well as the research proposed in this application. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations. This information should be coordinated with information provided under Sponsor and Co-Sponsor Statements, Training Plan, Environment, Research Facilities.

Additional Educational Information (required for F30 and F31 applications):

Describe the institution's dual-degree (F30) or graduate (F31) program in which the applicant is enrolled, e.g. the structure of the program, required milestones and their usual timing (number of courses, any teaching commitments, qualifying exams, etc.) and the average time to degree over the past 10 years. Describe the progress/status of the applicant in relation to the program's timeline, and the frequency and method by which the program formally monitors and evaluates a student's progress.

This information is typically provided by the director of the graduate program or the department chair. Include the name of the individual providing this information at the end of the description.

Note that a listing of the applicant's courses and grades must be included in the Fellowship Applicant Biographical Sketch, and NOT in this attachment.

Attach this information as a PDF file.

Other Research Training Plan Section

Human Subjects

Prefilled from the Research and Related Other Project Information form.

If activities involving human subjects are *not* planned at any time during the proposed project at any performance site, skip the remainder of the block and continue to Other Research Training Plan Sections.

If you have indicated "Yes" for Human Subjects involvement, consult with your Sponsor and Administrative Officials at the Sponsoring Institution before completing this section, and refer to Supplemental Instructions, Part II Section 4.1.

Human subjects requirements may apply even if you are obtaining specimens/data from collaborators or if you are subcontracting the human research to another organization. For all research involving human subjects, a part of the peer review process will include careful consideration of protections from research risks, as well as the appropriate inclusion of women, minorities, and children. The Scientific Review Group (SRG) will assess the adequacy of safeguards of the rights and welfare of research participants, and the appropriate inclusion of women, minorities, and children, based on the information in the application. The evaluation of the inclusion plans will be factored into the overall score that the SRG awards for scientific and technical merit of the application. Much of the information on the protection of human subjects that you are required to provide in the Fellowship application is identical to information that you will be required to provide for IRB review at your own institution.

Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.

12. Human Subjects Involvement Indefinite?

Check "Yes" if at the time of application plans to involve human subjects are unknown. If an award is made, you may not participate in human subjects research until an updated research training plan is

submitted and approved by the awarding component. Such a plan must be developed in consultation with your sponsor. Certification of the date of IRB approval must also be submitted before the fellow can participate in human subjects research.

13. Clinical Trial

Check "Yes" or "No" to indicate whether the project includes a clinical trial. See <u>Supplemental Instructions</u>, <u>Part III Section 3</u> for the specific definition.

14. Agency-Defined Phase III Clinical Trial?

Check the "Yes" or "No" box to indicate whether the project is an NIH-defined Phase III clinical trial. An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of either evaluating an experimental intervention in comparison with a standard or control intervention or of comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

15. Protection of Human Subjects

Refer to Supplemental Instructions, Part II Section 4.1.

This section is required for applicants answering "yes" to the question "Are human subjects involved?" on the <u>R&R Other Project Information Form</u>. If the answer is "No" to the question but the proposed research involves human specimens and/or data from subjects applicants must provide a justification in this section for the claim that no human subjects are involved.

Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.

Attach this information as a PDF file.

16. Data Safety Monitoring Plan

Complete this section if you answered "yes" to <u>Item 13</u> in this form. Refer to <u>Supplemental Instructions</u>, Part II Section 4.1.

Attach this information as a PDF files.

17. Inclusion of Women and Minorities

This section is required for applicants answering "yes" to the question "Are human subjects involved?" on the <u>R&R Other Project Information form</u> and the research does not fall under Exemption 4. Refer to <u>Supplemental Instruction</u>, <u>Part II Section 4.1</u>.

Attach this information as a PDF file.

18. Inclusion of Children

For applicants answering "Yes" to the question "Are human subjects involved" on the <u>R&R Other</u> <u>Project Information Form</u> and the research does not fall under Exemption 4, this section is required. Refer to Supplemental Instructions, Part II Section 4.1, 4.4 and 5.7

Attach this information as a PDF file.

Are Vertebrate Animals Used?

Prefilled from the Research and Related Other Project Information form.

Indicate 'No' and skip items 19 and 20 below if activities involving vertebrate animals are not planned at any time during the proposed project at any performance site.

19. Vertebrate Animals Use Indefinite?

Check "Yes" if plans for the involvement of vertebrate animals have not been finalized at the time of application making an IACUC review and approval not feasible at this stage. However, if an award is made, vertebrate animals may not be used until a verification of the date of IACUC approval has been submitted to the NIH IC or AHRQ.

20. Are animals euthanized?

Check "Yes" or "No" to indicate whether animals in the project are euthanized or not.

If "Yes" to euthanasia: Is method consistent with AVMA guidelines?

Check "Yes" or "No" to indicate whether the method of euthanasia is consistent with the American Veterinary Medical Association Guidelines for the Euthanasia of Animals. See https://www.avma.org/KB/Policies/Pages/Euthanasia-Guidelines.aspx for more information.

If "No" to AVMA guidelines, describe method and provide a scientific justification:

If you answered "No" to the question "Is method consistent with AVMA guidelines?" describe the method of euthanasia and provide a scientific justification for its use. If you answered "Yes", leave the section blank.

21. Vertebrate Animals

This section is required for applicants answering "Yes" to the question "Are vertebrate animals involved?" on the R&R Other Project Information Form.

If Vertebrate Animals are involved in the project, address each of the following criteria listed below.

- Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the "Research Strategy" section. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed provide the source of the animals.
- 2. Justifications: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro).
- 3. Minimization of Pain and Distress: Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain, and injury.

For additional information, see http://grants.nih.gov/grants/olaw/VASchecklist.pdf. Do not use the Vertebrate Animals section to circumvent the page limits of the Research Strategy.

Provide a concise, complete description of the animals and proposed procedures.

- The responses to the criteria below must be well-integrated with the other sections. There should be sufficient detail in the responses for peer reviewers and NIH staff to evaluate. Additional details, if any, may be included in the Research Strategy.
- Identify all project/performance or collaborating site(s) and describe activities of proposed research with vertebrate animals in those sites.
- An incomplete application will not be considered for review. It will be considered incomplete if the following criteria are not addressed.
- If plans for the use of animals have not been finalized, explain when and how animals are expected to be used.
- If an award is made, the grantee must provide detailed information on the criteria below, and verification of IACUC approval. These must be submitted to the NIH awarding office prior to the involvement of animals.

An applicable Animal Welfare Assurance will be required if the grantee institution does not have one (see Supplemental Instructions, Part III Section 2.2 for more information).

Attach this information as a PDF file.

Other Research Training Plan Information

Consult with your Sponsor and Administrative Officials at the Sponsoring Institution before completing Items 22 through 24.

22. Select Agent Research

Select agents are hazardous biological agents and toxins that have been identified by DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC maintains a list of these agents. See http://www.cdc.gov/od/sap/docs/salist.pdf.

If the activities proposed in the application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.3, the select agent requirements do not apply. Use this section to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions at http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html.

If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to HHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.

If any of the activities proposed in your application involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which select agent research will take place. Although no specific page limitation applies to this section, be succinct.

- 1. Identify the select agent(s) to be used in the proposed research.
- 2. Provide the registration status of all entities* where select agent(s) will be used.
 - If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed.
 - *An "entity" is defined in 42 CFR 73.1 as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity."
- 3. Provide a description of all facilities where the select agent(s) will be used.
 - Describe the procedures that will be used to monitor possession, use and transfer of select agent(s).
 - Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s).
 - Describe the biocontainment resources available at all performance sites.

If you are responding to a specific funding opportunity announcement, address any requirements specified by the FOA.

Reviewers will assess the information provided in this Section, and any questions associated with select agent research will need to be addressed prior to award.

Attach this information as a PDF file.

23. Resource Sharing Plan(s)

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Supplemental Instructions, Part III Section 1.5.

Attach this information as a PDF file.

24. Authentication of Key Biological and/or Chemical Resources

Do not include an attachment in this field; this is not yet required.

Additional Information Section

25. Human Embryonic Stem Cells

Indicate "Yes" if the proposed research involves human embryonic stem cells. See http://stemcells.nih.gov/info/basics/pages/basics3.aspx for a definition of human embryonic stem cells, list in this section the 4-digit NIH Registration Number of the specific cell line(s) from the NIH Human Embryonic Stem Cell Registry found at: http://grants.nih.gov/stem_cells/registry/current.htm. If a specific stem cell line cannot be referenced at the time of application submission, check the box provided to indicate that one from the registry will be used.

26. Alternate Phone Number

Enter an alternate phone number (e.g., cell phone) where the fellowship applicant can be reached on matters relating to this application for fellowship support. This should be a different number than provided in the PD/PI contact information in the SF424 (R&R) Form.

27. Degree Sought During Proposed Award

Complete if applicable. If you will be working toward a degree while receiving fellowship support, select the type of degree from the drop-down menu. If the degree is not on the drop down menu, please select "Other" and indicate the type of degree in the space provided.

28. Field of Training for Current Proposal

Select a single Field of Training code from the drop-down menu that best describes the proposed area of research training. This information is used for reporting purposes only and is not used for study section assignments.

29. Current or Prior Kirschstein-NRSA Support?

If "Yes", identify the current and/or prior Kirschstein-NRSA support from the drop down menu, up to four entries. Define level of support as either predoctoral or postdoctoral level (not the level of experience). The type of support is either individual fellowship or institutional research training grant. Enter the start and end dates (if known) of the support (month, day, and year) and the grant number (if known) of the current and/or prior support (e.g., T32 GM123456 or F31 HL345678).

An individual cannot receive more than 5 years of cumulative predoctoral Kirschstein-NRSA support and 3 years cumulative postdoctoral Kirschstein-NRSA support (the total of Institutional Grants and Individual Fellowships) without a waiver from the awarding component. The awarding components have different policies on waiving the statutory limits on support. Therefore, the fellowship applicant must request a waiver from the probable funding IC before requesting a period of support that would exceed these limits. The fellow's sponsor and a sponsoring institution official must endorse the request, and it must include justification and specify the amount of additional support for which approval is sought. Individuals seeking additional support beyond the third year of postdoctoral support are strongly advised to consult with their awarding IC Program Officer before submitting a waiver request. It is important to read carefully the applicable FOA that may have an overall approval to exceed these limits (e.g., the F30) programs allow for up to 6 years of predoctoral support).

Promptly report to the awarding component to which this application is assigned any additional NRSA support received while this application is pending.

30. Applications for Concurrent Support?

Check the appropriate answer, indicating "Yes" if the fellowship applicant has applied or will be applying for other support that would run concurrently with the period covered by this application. Include the type, dates, source(s) and amount in the attachment document, if applicable. The fellowship applicant must promptly report to the NIH IC to which this application is assigned, or AHRQ, any support resulting from other such applications.

Attach this information as a PDF file.

31. Citizenship

To be eligible for a Kirschstein-NRSA Individual Fellowship (F30, F31, F32, F33), the fellowship applicant must be a U.S. citizen, a non-citizen national, or have been lawfully admitted to the U.S. for permanent residence before the award is issued. Individuals on temporary student visas are not eligible for NRSA support.

If the fellowship applicant is applying for a non-NRSA fellowship program supported by the NIH, for which citizenship or permanent residency is not required (e.g., Fogarty International Center programs), the fellowship applicant must have in his/her possession a valid visa allowing him/her to remain in the U.S. (or in a foreign research training setting, if applicable) long enough to be productive on the proposed fellowship project. It is the responsibility of the sponsoring institution to determine and retain documentation indicating that the individual fellowship applicant's visa will allow him/her to reside in the proposed research training setting for the period of time necessary to complete the proposed fellowship.

U.S. Citizen or Non-Citizen National:

Check this box if the applicant is a U.S. citizen or non-citizen national. Non-citizen nationals are people, who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are people born in outlying possessions of the United States (e.g., American Samoa and Swains Island).

Non-U.S. Citizen With a Permanent U.S. Resident Visa:

Check this box if the applicant has been lawfully admitted for permanent residence; i.e., is in the possession of a current and valid Permanent Resident Card (USCIS Form I-551) or other legal

verification of such status.

Before the award is issued, a permanent resident will be required to submit a notarized statement that a licensed notary has seen the fellowship applicant's valid Permanent Resident Card (USCIS Form I-551) or other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S.

Non-U.S. Citizen With a Temporary U.S. Visa:

Check this box if the fellowship applicant is a non-citizen holding a temporary U.S. visa.

If the applicant has applied for permanent residence and expects to hold a permanent resident visa by the earliest possible start date of the award, please also check the box at the bottom of the form indicating that permanent residence status is pending. A notarized statement will be required as a part of the pre-award process

32. Change of Sponsoring Institution

Indicate if this application is being submitted with a change of sponsoring institution. If the box is checked, the name of the former sponsoring institution must be provided.

Budget Section

All Fellowship Applicants:

1. Tuition and Fees

All fellowship applicants should list the estimated costs of tuition and fees. Postdoctoral and senior fellowship applicants should list the costs associated with courses planned that support the research training experience and are identified and described in the attachment for the Applicant's Background and Goals for Fellowship Training, under "Activities Planned Under This Award." If no tuition and fees are being requested, check the box provided.

With the exception of senior fellowship applicants, no additional budget information is required. The final stipend and institutional allowance will be determined at the time of award.

In accordance with NIH Guide <u>NOT-OD-10-073</u>, funds to offset the costs of health insurance (self or family, as appropriate) are included in the standard Institutional Allowance, and not to be requested as part of Tuition and Fees.

Senior Fellowship Applicants Only:

2. Present Institutional Base Salary

Senior fellowship applicants must provide their present base salary and indicate the period of time on which the salary is determined (e.g., academic year of 9 months, full-time 12 months, etc. The number may not be more than 12, but may include a decimal indicating partial months (e.g., 9.5).

3. Stipend/ Salary During First Year of Proposed Fellowship

A. Federal Stipend Requested:

Fellowship applicants must insert the stipend being requested for the initial period of support and the number of months.

B. Supplementation from other sources:

Fellowship applicants should enter the anticipated amount and the length of time associated with the amount. Enter also the type of supplementation expected (e.g., salary, sabbatical leave, etc.) and the source of such funding.

Appendix

Appendix

A maximum of 10 PDF attachments is allowed in the appendix. If more than 10 appendix attachments are needed, combine the remaining information into attachment #10. Note that this is the total number of appendix items, not the total number of publications.

Do not use the appendix to circumvent the page limits of the research strategy or any other section of the application for which a page limit applies. For additional information regarding appendix material and page limits, please refer to NOT-OD-11-080.

Use filenames for attachments that are descriptive of the content. A summary sheet listing all of the items included in the appendix is also encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment. Applications that do not follow the appendix requirements will not be reviewed.

Applications may include the following materials in the appendix (note, however, that some FOAs do not permit publications):

- Publications No longer allowed as appendix materials except in the circumstances noted below.
 Applicants may submit up to 3 of the following types of publications:
 - Manuscripts and/or abstracts accepted for publication but not yet published: The entire article should be submitted as a PDF attachment.
 - Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available: The entire article should be submitted as a PDF attachment.
- Patents directly relevant to the project: The entire document should be submitted as a PDF attachment.
- Surveys, questionnaires, and other data collection instruments; clinical protocols, and informed consent documents may be submitted in the appendix as necessary

For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g., medical devices, prototypes, DVDs, CDs), applicants should contact the Scientific Review Officer for instructions following notification of assignment of the application to a study

section. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.

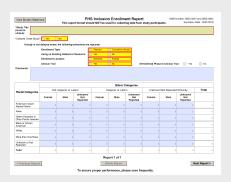
Items that must **not** be included in the appendix:

- Unpublished theses or abstracts/manuscripts submitted (but not yet accepted) for publication.
- Digital photographs or color images of gels, micrographs, etc. are no longer accepted as appendix material. These images must be included in the Research Strategy PDF. However, images embedded in publications are allowed.
- Publications that are publicly accessible. For such publications, the URL or PMC submission
 identification numbers along with the full reference should be included as appropriate in the
 Bibliography and References cited section, the Progress Report Publication List section, and/or the
 Biographical Sketch section.

F.500 - PHS Inclusion Enrollment Report

The PHS Inclusion Enrollment Report form is used for all applications involving NIH-defined clinical research. This form is used to report both planned and cumulative (or actual) enrollment, and describes the sex/gender, race, and ethnicity of the study participants.

NOTE: This report format should NOT be used for collecting data from study participants. To ensure proper performance of the form, please save frequently.



See below for the forms descriptions and please refer to <u>Supplemental Instructions</u>, <u>Part II Section 4.3</u> for additional guidance on how and when to use the PHS Inclusion Enrollment Report.



Study Title:

Enter a unique title that describes the study that the participants will be involved in. If there is more than one study, provide a separate Study Title for each. Follow the instructions provided in the Application Guide and the FOA regarding the Inclusion of Women and Minorities. Maximum 250 characters. This is a required field.

Delayed onset study?

Select whether the study is considered delayed onset. This generally means that a study has not been developed and cannot be described in terms of human subjects' protections and inclusion. This does NOT apply to a study that can be described but will not start immediately. Additional guidance on whether a study meets the criteria to be considered delayed onset can be found in Section 2, Scenario D of the <u>Supplemental Instructions</u>, <u>Part II.</u> If the study is delayed onset, select YES. If the study is not delayed onset, select NO. This is a required field.

If you have answered "No" to delayed onset, you must answer the following and complete the enrollment table:

Enrollment Type:

Select whether the table reflects Planned Enrollment of individuals to be recruited into the study or Cumulative (e.g., actual) Enrollment for 1) participants already recruited into the study or 2) studies using an existing dataset or resource. This is a required field.

Using an existing dataset or resource?

Select whether this study involves use of an existing dataset or resource. This generally means that investigators are utilizing data from a previous study or data bank. Do NOT answer Yes for individuals previously recruited specifically for this study. For additional guidance on what is considered an existing dataset refer to Supplemental Instructions, Part II Section 4.2 and this FAQ. This is a required field.

Enrollment Location:

Select whether the participants described in the inclusion enrollment report are based at a US or non-US site. At a minimum, participants at US and non-US sites must be reported separately even if for the same study. For additional guidance on working with non-US populations refer to this FAQ. This is a required field.

Clinical Trial:

Select whether the study these participants are involved in is considered a <u>clinical trial</u>. This is a required field.

Agency-Defined Phase III Clinical Trial:

Select whether the study is an agency-defined Phase III clinical trial. This is a required field.

Comments:

Enter information you wish to provide about this PHS Inclusion Enrollment report. This includes but is not limited to addressing information about distinctive subpopulations if relevant to the scientific hypotheses being studied and/or a study that will have a delayed onset. Maximum 500 characters.

Racial Categories:

American Indian/Alaska Native:

Enter the expected number of females and males (in the respective fields) who are American Indian/Alaska Native and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are American Indian/Alaska Native and Hispanic or Latino. Unknown/not reported fields will only be used when reporting actual enrollment on "Enrollment Type" Cumulative. These are required fields.

Asian:

Enter the expected number of females and males (in the respective fields) who are Asian and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are Asian and Hispanic or Latino. Unknown/not reported fields will only be used when reporting actual enrollment on "Enrollment Type" Cumulative. These are required fields.

Native Hawaiian or Other Pacific Islander:

Enter the expected number of females and males (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Hispanic or Latino. Unknown/not reported fields will only be used when reporting actual enrollment on "Enrollment Type" Cumulative. These are required fields.

Black or African American:

Enter the expected number of females and males (in the respective fields) who are Black or African American and Not Hispanic or Latino, and; Enter the expected number of females and males (in the respective fields) who are Black or African American and Hispanic or Latino. Unknown/not reported fields will only be used when reporting actual enrollment on "Enrollment Type" Cumulative. These are required fields.

White:

Enter the expected number of females and males (in the respective fields) who are White and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are White and Hispanic or Latino. Unknown/not reported fields will only be used when reporting actual enrollment on "Enrollment Type" Cumulative. These are required fields.

More than One Race:

Enter the expected number of females and males (in the respective fields) who identify with more than one racial category and are Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who identify with more than one racial category and are Hispanic or Latino. Unknown/not reported fields will only be used when reporting actual enrollment on "Enrollment Type" Cumulative. These are required fields.

Unknown or Not Reported:

Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are of unknown/not reported race and of unknown/not reported ethnicity. Unknown/not reported fields will only be used when reporting actual enrollment on "Enrollment Type" Cumulative. These are required fields.

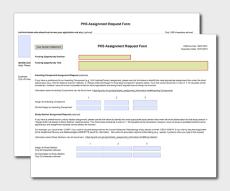
Total:

The total fields at the bottom are auto-calculated to total all racial categories for females, males and individuals of unknown/not reported sex/gender who are Not Hispanic or Latino and all racial categories for females, males and individuals of unknown/not reported sex/gender who are Hispanic or Latino. Unknown/not reported fields will only be used when reporting actual enrollment on "Enrollment Type" Cumulative. The total fields at the right are auto-calculated to total all individuals in a given racial category.

F.600 - PHS Assignment Request Form

The optional Assignment Request Form may be used to communicate specific application assignment and review requests to the Division of Receipt and Referral (DRR) and to Scientific Review Officers (SROs).

This information will not be part of your application, and it will not be made available to program staff or provided to reviewers. It is used specifically to convey additional, optional information about your preference(s) for assignment and review of your application to DRR and SROs.



This information was previously collected in the Cover Letter Attachment, but now, this optional information must be provided on the Assignment Request Form and not in the Cover Letter Attachment.



The Division of Receipt and Referral (DRR), Center for Scientific Review (CSR) is responsible for assigning applications to NIH institutes/centers (ICs) and other PHS agencies for funding consideration. DRR also assigns application to NIH scientific review groups (SRGs) and special emphasis panels (SEPs).

This form is optional and may be omitted from your application submission if you do not wish to make any specific assignment or review requests. There is no requirement that all fields in the form are completed; you have the flexibility to enter a single request or provide extensive information using this form.

Awarding Component Assignment Request (optional)

This section of the form is optional. You may request up to three institutes/centers for assignment of your application

Assign to Awarding Component:

Enter preferences for NIH IC assignment in the boxes in the "Assign to" row. Use the column labeled "1" to enter your first choice.

Do Not Assign to Awarding Component:

You may request that your application not be assigned to a specific NIH IC by entering that information in the boxes in the "Do Not Assign To" row.

In most cases, you will only want to make one or two requests; there is no need to make an entry in all six boxes. The hyperlink in this section of the form (http://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents) will take you to a web site where descriptions of the science covered by all NIH institute/centers can be found, including links to other PHS agency information.

To facilitate accurate communication of your request to NIH referral and review staff, please use the short abbreviation for the requested NIH IC (e.g., NCI for the National Cancer Institute). While NIH staff will seriously consider all assignment requests, in some cases the locus of review is predetermined and assignment requests cannot be honored.

Study Section Assignment Request (optional)

This section of the form is optional. You may request up to three SRGs or SEPs for assignment of your application.

For this section, you will need to accurately type in the short abbreviation of the SRG / SEP you wish to request. The hyperlink in this section of the form (http://grants.nih.gov/grants/phs_assignment_information.htm#StudySection) will take you to a site where you can find more information about how to identify CSR and NIH SRGs and SEPs, including their short abbreviations. For example, you would enter "CAMP" if you wish to request assignment to the Cancer Molecular Pathobiology study section or enter "ZRG1 HDM-R" if you wish to request assignment to the Healthcare Delivery and Methodologies SBIR/STTR panel for informatics. Be careful to accurately capture all formatting (e.g., spaces, hyphens) when you type in the request.

Assign to Study Section:

Enter the short abbreviations(s) for SRGs / SEPs to which you would like your application assigned in the "Assign to" row. Use one box per individual SRG/ SEP request. Type your first choice in the column labeled "1".

Do Not Assign to Study Section:

If you wish to request that your application not be assigned to a particular SRG/SEP, enter that information in the boxes found in the "Do Not Assign To" row.

In most cases, you will only want to make one or two requests; there is no need to make an entry in all six boxes.

Please note that while the majority of NIH research grant and fellowship applications are reviewed by the Center for Scientific Review (CSR), some are assigned to individual institute/center review groups and some applications are clustered for review in SRGS / SEPs without flexibility for honoring review requests. However, it is standard practice to honor such requests whenever possible, depending on existing locus of review agreements within NIH and other PHS agencies.

List individuals who should not review your application and why (optional)

Provide sufficient information (e.g., name, organizational affiliation) so that the SRO can correctly identify the individual, and provide sufficient information so that the SRO can confirm a conflict of interest for the review. Simply stating "Dr. John Smith is in conflict with my application" is not helpful. Maximum 1000 characters.

Identify expertise needed to review your application (optional)

Five fields are provided if you wish to identify general or specific types of expertise needed for the review of your application. Maximum 40 characters/field. Do not enter names of individuals you would like to review your application.

Form Screenshots

Quick Links

- SF 424 (R&R) Form
- R&R Other Project Information Form
- Project/Performance Site Location(s) Form
- R&R Senior/Key Persons Profile (Expanded)
- PHS Fellowship Supplemental Form
- PHS Inclusion Enrollment Report
- PHS Assignment Request Form

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SF 424 (R&R) Form

				OMB Number: 4040-0001
APPLICATION FOR FEDE	RAL ASSISTANCE		3. DATE RECEIVED BY STAT	E State Application Identifier
SF 424 (R&R)				
1. TYPE OF SUBMISSION			4. a. Federal Identifier	
Pre-application Applic	ation Changed/Co	orrected Application	b. Agency Routing Identifier	
2. DATE SUBMITTED	Applicant Identifier]	
			c. Previous Grants.gov Tracking ID	
S. APPLICANT INFORMATIO	N		Organizational DUNS:	
Legal Name:				
Department:		Division:		
Street1:				
Street2:				
City:		County / Paris	h:	
State:			Province:	
Country:	USA: UNITED	STATES	ZIP / Postal Cod	9:
Person to be contacted on mat	tters involving this appli	cation		
	First Name:		Middle Na	me:
Last Name:			Suffix:	
Position/Title:				
Street1:				
Street2:				
City:		County / Paris		
Starte:			Province:	
Country:	USA: UNITE		ZIP / Postal Co	ode:
Phone Number:		Fax Number:		
Email:				
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Email: EMPLOYER IDENTIFICATION TYPE OF APPLICANT:	ON (EIN) or (TIN):		e select one of the follo	owing
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SF 424 (R&R) APPLICATION FOR FEDERAL A	ssistance Page 2
14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT	
Prefix: First Name:	Middle Name:
Last Name:	Suffix:
Position/Title:	
Organization Name:	
Department: Division	:
Street1:	
Street2:	
City: County	/ Parish:
State:	Province:
Country: USA: UNITED STATES	ZIP / Postal Code:
Phone Number: Fax Number:	
Email:	
15. ESTIMATED PROJECT FUNDING	16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?
a. Total Federal Funds Requested	a. YES THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372
b. Total Non-Federal Funds	PROCESS FOR REVIEW ON:
c. Total Federal & Non-Federal Funds	DATE:
d. Estimated Program Income	b. NO PROGRAM IS NOT COVERED BY E.O. 12372; OR
<u></u>	PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW
terms if I accept an award. I am aware that any false, fictitious of administrative penalties. (U.S. Code, Title 18, Section 1001) lagree The list of certifications and assurances, or an internet site where you may obtain	
18. SFLLL (Disclosure of Lobbying Activities) or other Explanate	Add Attachment Delete Attachment View Attachment
19. Authorized Representative	
Prefix: First Name:	Middle Name:
Last Name:	Suffix:
Position/Title:	
Organization:	
Department: Division:	
Street1:	
Street2:	
City: County / Pa	arish:
State:	Province:
Country: USA: UNITED STATES	ZIP / Postal Code:
Phone Number: Fax Number:	
Email:	
Signature of Authorized Representative	Date Signed
Completed on submission to Grants.gov	Completed on submission to Grants.gov
20. Pre-application	Add Attachment Delete Attachment View Attachment
21. Cover Letter Attachment	Add Attachment Delete Attachment View Attachment

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Other Project Information Form

Expiration Date: 6/30/2016
1. Are Human Subjects Involved? 1.a. If YES to Human Subjects Is the Project Exempt from Federal regulations? Yes No
If yes, check appropriate exemption number. 1 2 3 4 5 6
If no, is the IRB review Pending? Yes No
IRB Approval Date:
Human Subject Assurance Number:
2. Are Vertebrate Animals Used? Yes No
2.a. If YES to Vertebrate Animals
Is the IACUC review Pending? Yes No
IACUC Approval Date:
Animal Welfare Assurance Number:
3. Is proprietary/privileged information included in the application?
4.a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment?
4.b. If yes, please explain:
4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? Yes No
4.d. If yes, please explain:
5. Is the research performance site designated, or eligible to be designated, as a historic place? Yes No
5.a. If yes, please explain:
8. Does this project involve activities outside of the United States or partnerships with international collaborators?
8.a. If yes, identify countries:
8.b. Optional Explanation:
7. Project Summary/Abstract Add Attachment Delete Attachment View Attachment
8. Project Narrative Add Attachment Delete Attachment View Attachment
9. Bibliography & References Cited Add Attachment Delete Attachment View Attachment
10. Facilities & Other Resources Add Attachment Delete Attachment View Attachment
11. Equipment Delete Attachment View Attachment
12. Other Attachments Add Attachments Delete Attachments View Attachments

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Project/Performance Site Location(s) Form

OMB Number: 4040-0010

	P	roject/Performance	Site Lo	ocation(s)	
Project/Performance	Site Primary Location	☐ I am submitting an ap local or tribal governr			l, and not on behalf of a company, state, type of organization.
Organization Name:					
DUNS Number:					
* Street1:					
Street2:					
* City:			County:		
* State:					
Province:					
* Country: USA: U	NITED STATES	<u> </u>			
* ZIP / Postal Code:			* Project	/ Performance	Site Congressional District:
Project/Performance	e Site Location 1				l, and not on behalf of a company, state,
Organization Name:		☐ local or tribal governr	nent, acad	emia, or other	type of organization.
DUNS Number:					
* Street1:					
Street2:					
* City:			County:		
* State:					
Province:					
* Country: USA: U	NITED STATES				
* ZIP / Postal Code:			* Project	/ Performance	Site Congressional District:
Additional Location	(s)		Add Attach	ment D	elete Attachment View Attachment

Form Screenshots F - v

Senior/Key Persons Profile (Expanded)

OMB Number: 4040-0001

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Inve	estigator
Prefix: * First Name:	Middle Name:
* Last Name:	Suffix:
Position/Title: Departmen	nt:
Organization Name:	Division:
* Street1:	
Street2:	
* City: County/ Parish:	
* State:	Province:
* Country:	* Zip / Postal Code:
* Phone Number: Fax Number:	
* E-Mail:	
Credential, e.g., agency login:	
* Project Role: PD/PI Other Project Role Categ	ory:
Degree Type:	
Degree Year:	
*Attach Biographical Sketch Add	Attachment Delete Attachment View Attachment
Attach Current & Pending Support Add	Attachment Delete Attachment View Attachment
	_
PROFILE - Senior/Key Person 1	ı
Prefix: * First Name:	Middle Name:
* Last Name:	Suffix:
Position/Title: Departmer	nt:
Organization Name:	Division:
* Street1:	
Street2:	
* City: County/ Parish:	
* State:	Province:
* Country: USA: UNITED STATES	* Zip / Postal Code:
* Phone Number: Fax Number:	
* E-Mail:	
Credential, e.g., agency login:	
* Project Role: Other Project Role Categ	lory:
Degree Type:	
Degree Year:	
	Attachment Delete Attachment View Attachment Attachment Delete Attachment View Attachment
Delete Entry	Next Person

To ensure proper performance of this form; after adding 20 additional Senior/ Key Persons; please save your application, close the Adobe Reader, and reopen it.

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PHS Fellowship Supplemental Form

PHS Fellowship Supplemental Form

				OMB Number: 0925-000
Introduction				
1. Inroduction (for Resubmission)		Add Attachment	Delete Attachment	View Attachment
Fellowship Applicant Section				
Applicant's Backround and Goals for Fellowship Training		Add Attachment	Delete Attachment	View Attachment
Research Training Plan Section				
3. Specific Aims		Add Attachment	Delete Attachment	View Attachment
Research Strategy		Add Attachment	Delete Attachment	View Attachment
5. Respective Contributions		Add Attachment	Delete Attachment	View Attachment
Selection of Sponsor and Institution		Add Attachment	Delete Attachment	View Attachment
7. Progress Report Publication List (for RENEWAL applications only)		Add Attachment	Delete Attachment	View Attachment
Training in the Responsible Conduct of Research		Add Attachment	Delete Attachment	View Attachment
Sponsor(s), Collaborator(s), and Consulta	ant(s) Section			
9. Sponsor and Co-Sponsor Statements		Add Attachment	Delete Attachment	View Attachment
10. Letters of Support from Collaborators, Contributors, and Consultants		Add Attachment	Delete Attachment	View Attachment
Institutional Environment and Commitme	ent to Training Section			
11. Description of Institutational Environment and Commitment to Training		Add Attachment	Delete Attachment	View Attachment

Form Screenshots F - vii

The following item is taken f to this item must be made of	rom the Resea on the Researc	rch & Related h & Related C	Other Po	Project Information for ject Information form	m and repe	ated here for you	r reference. Any	change
Are H	luman Subject	s Involved?		Yes No				
2. Human Subjects Involvement Indefinite?	☐ Yes	□ No						
13. Clinical Trial?	☐ Yes	☐ No						
14. Agency-Defined Phase III Clinical Frial?	☐ Yes	□ No						
15. Protection of Human Subjects				Add Attachme	nt D	elete Attachment	View Attac	nment
16. Data Safety Monitoring Plan				Add Attachme	nt D	elete Attachment	View Attac	nment
17. Inclusion of Women and Minorities				Add Attachme	nt D	elete Attachment	View Attac	hment
18. Inclusion of Children				Add Attachme	nt D	elete Attachment	View Attac	nment
The following item is taken to this item must be made		ch & Related	Other Pr	oject Information forn		eated here for yo	ur reference. Any	change
The following item is taken to this item must be made	on the Resear	ch & Related Animals Used	Other Pr			eated here for yo	ur reference. Any	change
The following item is taken to this item must be made	on the Resear	ch & Related Animals Usec	Other Pr	oject Information forn		eated here for yo	ur reference. Any	change
The following item is taken to this item must be made	on the Resear	ch & Related Animals Used	Other Pr	oject Information forn		eated here for yo	ur reference. Any	change
The following item is taken to this item must be made // 19. Vertebrate Animals Use Indefinite?	on the Resear Are Vertebrate. Yes Yes	Animals Used	Other Pr	oject Information form		eated here for yo	ur reference. Any	change
The following item is taken to this item must be made 19. Vertebrate Animals Use Indefinite? 20. Are animals euthanized? If "Yes" to euthanasia Is method consistent with Ar	on the Resear Are Vertebrate Yes Yes Presserrican Veteringes?	Animals Used No No No	Other Pr	oject Information form		eated here for yo	ur reference. Any	change
The following item is taken to this item must be made 19. Vertebrate Animals Use Indefinite? 20. Are animals euthanized? If "Yes" to euthanasia Is method consistent with Ar Association (AVMA) guidelin If "No" to AVMA guidelines, desprovide a scientific justification	on the Resear Are Vertebrate Yes Yes President Veteringes?	Animals Used No No No	Other Pr	oject Information form	n	eated here for yo	ur reference. Any	
The following item is taken to this item must be made 19. Vertebrate Animals Use Indefinite? 20. Are animals euthanized? If "Yes" to euthanasia Is method consistent with Ar Association (AVMA) guidelin If "No" to AVMA guidelines, desprovide a scientific justification	on the Resear Are Vertebrate Yes Yes nerican Veterines?	Animals Used No No No	Other Pr	oject Information form	n			
The following item is taken to this item must be made to this item must be made 19. 19. Vertebrate Animals Use Indefinite? 20. Are animals euthanized? If "Yes" to euthanasia Is method consistent with Ar Association (AVMA) guideline if "No" to AVMA guidelines, desprovide a scientific justification 21. Vertebrate Animals Other Research Training Plan Information	on the Resear Are Vertebrate Yes Yes nerican Veterines?	Animals Used No No No	Other Pr	oject Information form	n. Delet			ent
to this item must be made 19. Vertebrate Animals Use Indefinite? 20. Are animals euthanized? If "Yes" to euthanasia Is method consistent with Ar Association (AVMA) guidelin If "No" to AVMA guidelines, des	on the Resear Are Vertebrate Yes Yes nerican Veterines?	Animals Used No No No	Other Pr	oject Information form	Delet	e Attachment	View Attachm	ent

Form Screenshots F - viii

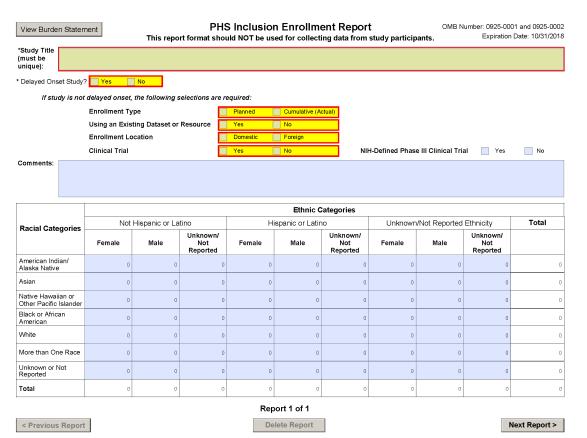
Additional Information Section
25. Human Embryonic Stem Cells
* Does the proposed project involve human embryonic stem cells?
If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following llist: http://stemcells.nih.gov/research/registry/, Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:
Specific stem cell line cannot be referenced at this time. One from the registry will be used.
Cell Line(s) (Example:0004): Add
26. Alternate Phone Number
27. Degree Sought During Proposed Award:
Degree If "other", please indicate degree type If "other", please indicate degree type Expected Completion Date (MM/YYYY):
28.*Field of Training for Current Proposal 29. *Current or Prior Kirschstein-NRSA Support? Yes No If yes, please identify current and prior Kirschstein-NRSA support below:
* Level * Type Start Date (if known) End Date (if known) Grant Number (if known) Reset Entry
Add 30. *Applications for Concurrent Support?
31. * Citizenship U.S. Citizen U.S. Citizen or Non-Citizen National Non-U.S. Citizen With a Permanent U.S. Resident Visa With a Temporary U.S. Visa If you are a non-U.S. citizen with a temporary visa who has applied for permanent resident status and expects to hold a permanent resident visa by the earliest possible start date of the award, please also check here.
Name of Former Institution 32. Change of Sponsoring Institution

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All Fellowship Applicants:						
1. * Tuition and Fees: None Re	quested 🔲 Fun	ds Requested	t			
Yea	r 1					
Yea	r 2					
Yea	r 3					
Yea	г 4					
Yea	r 5					
Yea	r 6 (if applicable)					
Tota	al Funds Requested:					
Senior Fellowship Applicants Only			Academic Period			
2. Present Institutional Base Salary:	Amount		Academic Feriod	Numb	ber of Months	Reset Entry
Stipends/Salary During First Year of Proposed Fellowship						
a. Federal Stipend Requested:	Amount		Number of Months			
a. I edelai Supelid Requested.	Amount		Number of Months			
 Supplementation from other sources: 	Amount		Number of Months			
	Type (sabbatical leave	, salary, etc.)				
	Source					1

Form Screenshots F - x

PHS Inclusion Enrollment Report



To ensure proper performance, please save frequently.

Form Screenshots F - xi

PHS Assignment Request Form

View Burden Statement		PHS Assignment Req	uest Form		3 Number: 0925-0001 tion Date: 10/31/2018
Funding Opportunity Number:					
Funding Opportunity Title:					
ranang opportunity ritie.					
Awarding Component Assignment Rec	quest (optional)				
If you have a preference for an Awarding abbreviation (e.g., NCI for National Cance considered; however, locus of review is present the considered of the co	er Institute) in "Assign to/D	o Not Assign To Awarding Compon-	ent" sections below. Your fire		
Information about Awarding Components	can be found here: https:/	/grants.nih.gov/grants/phs_assignm	ent_information.htm#Awardi	ng Components	
	1	2	3		
Assign to Awarding Component:					
Do Not Assign to Awarding Component:					
Study Section Assignment Request (o)	otional)				
If you have a preference for a study section 'Assign to/Do not Assign to Study Section' applications and assignment requests car	" sections below. Your firs	the link below to identify the most a choice should be in column 1. All r	ppropriate study section the equests will be considered; I	n enter the short abbreviation for nowever, locus of review is prec	r that study section in etermined for some
For example, you would enter "CAMP" if y to the Healthcare Delivery and Methodolo					
nformation about Study Sections can be					
	1	2	3		
Assign to Study Section: Only 20 characters allowed					
Do Not Assign to Study Section: Only 20 characters allowed					
only 20 onaradicro anovica					
		PHS Assignment Re	quest Form		
st Individuals who should not review	your application and w	hy (optional)			Only 1000 characters allov
					•
entify Scientific areas of expertise ne ote: Please do not provide names of ind		olication (optional)			
	1	2	3	4	5
		-	-	•	-

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